

# Exhibit B

Page 1

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2 UNITED STATES DISTRICT COURT  
3 FOR THE DISTRICT OF NEW JERSEY  
4 CAMDEN VICINAGE  
5

6 IN RE: VALSARTAN, LOSARTAN, AND MDL NO.  
7 IRBESARTAN PRODUCTS LIABILITY 2875  
8 LITIGATION  
9

10 This Document Relates to All Actions  
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14 CONFIDENTIAL VIDEOTAPED DEPOSITION  
15 OF  
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17 KALIOPI PANAGOS, PharmD, R.Ph.  
18 Wednesday, January 11, 2023  
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23 REPORTED BY:  
24 LINDA J. GREENSTEIN  
25

<p style="text-align: right;">Page 2</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 January 11, 2023  3 10:20 A.M.  4  5  6  7 Confidential Videotaped  8 Deposition of Kaliopi Panagos, PharmD,  9 R.Ph., taken by Defendants, held at  10 Lieff Cabraser Heimann &amp; Bernstein,  11 LLP, 250 Hudson Street, 8th Floor,  12 New York, New York 10013, before Linda  13 J. Greenstein, a Certified Shorthand  14 Reporter and Notary Public of the  15 States of New York and New Jersey.  16  17  18  19  20  21  22  23  24  25</p>	<p style="text-align: right;">Page 4</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 A P P E A R A N C E S: (Continued)  3  4 LIEFF CABRASER HEIMANN &amp; BERNSTEIN, LLP  Counsel on behalf of Plaintiffs  5 250 Hudson Street  New York, New York 10013  6  BY: RACHEL J. GEMAN, ESQ.  7 rgeman@lchb.com  8  9 KANNER &amp; WHITELEY, LLC  Counsel on behalf of Plaintiffs  10 701 Camp Street  New Orleans, Louisiana 70130  11  BY: CONLEE S. WHITELEY, ESQ.  12 c.whiteley@kanner-law.com  (Appearing Via Zoom)  13  14  HONIK, LLC  15 Counsel on behalf of Plaintiffs  1515 Market Street  16 Suite 1100  Philadelphia, Pennsylvania 19102  17  BY: RUBEN HONIK, ESQ.  18 ruben@honiklaw.com  (Appearing Via Zoom)  19  20  LEVIN PAPANTONIO RAFFERTY  21 Counsel on behalf of Plaintiffs  316 South Baylen Street  22 Pensacola, Florida 32502  23 BY: DANIEL NIGH, ESQ.  dnigh@levinlaw.com  24 (Appearing Via Zoom)  25</p>
<p style="text-align: right;">Page 3</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 A P P E A R A N C E S:  3  4 RIVERO MESTRE, LLP  Counsel on behalf of Plaintiffs  5 2525 Ponce de Leon Boulevard  Suite 1000  6 Miami, Florida 33134  7 BY: JORGE MESTRE, ESQ.  jmestre@riveromestre.com  8  ZALMAN KASS, ESQ.  9 zkass@riveromestre.com  10  11 PRETI FLAHERTY BELIVEAU &amp; PACHIOS  CHARTERED, LLP  12 Counsel on behalf of Maine Automobile  Dealers Association and the Plaintiffs  13 One City Center  Portland, Maine 04101  14  BY: GREGORY P. HANSEL, ESQ.  15 ghansel@preti.com  16 ELIZABETH F. QUINBY, ESQ.  equinby@preti.com  17  18  HOLLIS LAW FIRM  19 Counsel on behalf of Plaintiffs  8101 College Boulevard  20 Suite 260  Overland Park, Kansas 66210  21  BY: C. BRETT VAUGHN, ESQ.  22 brett@hollislawfirm.com  (Appearing Via Zoom)  23  24  25</p>	<p style="text-align: right;">Page 5</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 A P P E A R A N C E S: (Continued)  3  4 GREENBERG TRAURIG, LLP  Counsel on behalf Defendant of Teva  5 Pharmaceuticals USA, Inc.  One Vanderbilt Avenue  6 New York, New York 10017  7 BY: NILDA M. ISIDRO, ESQ.  Nilda.Isidro@gtlaw.com  8  GREGORY COATES, ESQ.  9 Coatesg@gtlaw.com  10 ANGELICA HALAT, ESQ.  Halata@gtlaw.com  11 (Appearing Via Zoom)  12 - AND -  13 WALSH PIZZI O'REILLY FALANGA, LLP  Counsel on behalf of Defendant Teva  14 Pharmaceuticals  Three Gateway Center  15 100 Mulberry Street  15th Floor  16 Newark, New Jersey 07102  17 BY: CHRISTINE I. GANNON, ESQ.  cgannon@walsh.law  18 (Appearing Via Zoom)  19  20 SKADDEN ARPS SLATE MEAGHER &amp; FLOM, LLP  Counsel on behalf of Defendant ZHP  21 155 N. Wacker Drive  Chicago, Illinois 60606  22  BY: ALEXANDER J. KASPARIE, ESQ.  23 alexander.kasparie@skadden.com  (Appearing Via Zoom)  24  25</p>

<p style="text-align: right;">Page 6</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 A P P E A R A N C E S: (Continued)  3  4 KIRKLAND &amp; ELLIS, LLP  Counsel on behalf of Defendant Torrent  5 601 Lexington Avenue  New York, New York 10022  6  BY: BRITTNEY NAGLE, Esq.  7 brittney.nagle@kirkland.com  (Appearing Via Zoom)  8  9  BUCHANAN INGERSOLL &amp; ROONEY, PC  10 Counsel on behalf of Defendant Albertsons,  LLC  11 Carillon Tower  227 West Trade Street - Suite 600  12 Charlotte, North Carolina  28202-2601  13  BY: CHRISTOPHER B. HENRY, ESQ.  14 christopher.henry@bipc.com  (Appearing Via Zoom)  15  16  HUSCH BLACKWELL  17 Counsel on behalf of Defendant Express  Scripts  18 190 Carondelet Plaza, Suite 600  St. Louis, Missouri 63105  19  BY: MATTHEW D. KNEPPER, ESQ.  20 matt.knepper@huschblackwell.com  (Appearing Via Zoom)  21  22  23  24  25</p>	<p style="text-align: right;">Page 8</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 A P P E A R A N C E S: (Continued)  3  4 FALKENBERG IVES, LLP  Counsel on behalf of Defendant Humana  5 Pharmacy, Inc.  230 West Monroe Street  6 Suite 2220  Chicago, Illinois 60606  7  BY: KIRSTIN B. IVES, ESQ.  8 kbi@falkenbergives.com  (Appearing Via Zoom)  9  10  11 Also Present:  12 Phil Glauberson, Veritext Videographer  13 Ben Pelta-Heller, Veritext Concierge  14  15  16  17  18  19  20  21  22  23  24  25</p>
<p style="text-align: right;">Page 7</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 A P P E A R A N C E S: (Continued)  3  4 PIETRAGALLO GORDON ALFANO BOSICK &amp;  RASPANTI, LLP  5 Counsel on behalf of Defendants Mylan  Laboratories Limited and Mylan  6 Pharmaceuticals, Inc.  1818 Market Street  7 Philadelphia, Pennsylvania 19103  8 BY: FRANK H. STOY, ESQ.  FHS@Pietragallo.com  9 (Appearing Via Zoom)  10  11 LEWIS BRISBOIS BISGAARD &amp; SMITH, LLP  Counsel on behalf of Defendant Camber  12 Pharmaceuticals  550 E. Swedesford Road  13 Suite 270  Wayne, Pennsylvania 19087  14  BY: ASHER A. BLOCK, ESQ.  15 Asher.Block@lewisbrisbois.com  (Appearing Via Zoom)  16  17  HILL WALLACK, LLP  18 Counsel on behalf of Defendants Hetero  Drugs Limited and Hetero Labs Limited  19 21 Roszel Road  Princeton, New Jersey 08540  20  BY: WILLIAM P. MURTHA, JR., ESQ.  21 wmurtha@hillwallack.com  (Appearing Via Zoom)  22  23  24  25</p>	<p style="text-align: right;">Page 9</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 THE VIDEOGRAPHER: Good morning.  3 We are going on the record at  4 10:20 a.m., 1/11/23.  5 Please note that microphones are  6 sensitive and may pick up whispering and  7 private conversations.  8 Please mute your phones at this  9 time and please place them away from the  10 microphones as they can interfere with the  11 audio.  12 Audio and video recording will  13 continue to take place unless all parties  14 agree to go off the record.  15 This is Media Unit 1 of the  16 video-recorded deposition of Dr. Kali  17 Panagos in the Matter of In Re Valsartan,  18 Losartan and Irbesartan Products Liability  19 Litigation filed in the United States  20 District Court, District of New Jersey,  21 Camden, 1:19-MD-02875.  22 The location of this deposition  23 is Lieff Cabraser Heimann &amp; Bernstein, 250  24 Hudson Street, New York, New York.  25 My name is Phil Glauberson</p>

<p style="text-align: right;">Page 10</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 representing Veritext and I am the  3 videographer.  4 The court reporter is Linda  5 Greenstein from Veritext.  6 I am not authorized to  7 administer an oath, I am not related to any  8 party in this action, nor am I financially  9 interested in the outcome.  10 All appearances will be noted on  11 the stenographic record.  12 Will the court reporter please  13 swear in the witness.  14 KALIOPI PANAGOS, PharmD, R.Ph.,  15 having been first duly sworn/affirmed, was  16 examined and testified as follows:  17 EXAMINATION BY  18 MS. ISIDRO:  19 Q. Good morning, Dr. Panagos. I'm  20 Nilda Isidro from the law firm of Greenberg  21 Traurig and I represent the Teva defendants  22 in this litigation.  23 A. Good morning.  24 Q. Could you please state your full  25 name for the record.</p>	<p style="text-align: right;">Page 12</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 very important that when you answer you  3 give me a verbal yes or no rather than  4 simply nodding your head or saying "uh-hum"  5 or "uh-uh" and that's just so that the  6 court reporter can take down a clear  7 transcript.  8 Okay?  9 A. Understood.  10 Q. And if at any time you don't  11 understand my question, please let me know.  12 If you do answer my question, I  13 will assume that you understood it.  14 Fair enough?  15 A. Yes.  16 Q. And if you need a break at any  17 time, again, please let me know.  18 I'll just ask that if there's a  19 question pending, that that question be  20 answered before we take the break.  21 A. Yes.  22 Q. Okay. Any questions about any  23 of that before we proceed?  24 A. No.  25 Q. Okay. Dr. Panagos, what is your</p>
<p style="text-align: right;">Page 11</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 A. Kali Panagos.  3 Q. Thank you. And you and I met  4 previously when I took your deposition in  5 this litigation last year; correct?  6 A. We did, yes, correct.  7 Q. So I know you've been deposed  8 before, but since it's been a while let's  9 go through the process again and just go  10 over some of the ground rules and how this  11 is going to work today.  12 I am going to be asking you some  13 questions which you're answering on the  14 record.  15 As you can see, the court  16 reporter to my right is taking down  17 everything that we say so for that reason  18 it's very important that we not talk over  19 each other, so please wait until I finish  20 my question before you start to answer and  21 I'll do the same. I'll wait until you  22 finish your answer before starting my next  23 question. Okay?  24 A. Of course.  25 Q. And for the same reason, it's</p>	<p style="text-align: right;">Page 13</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 current professional address?  3 A. 105 Down Court, Windermere,  4 Florida.  5 Q. Is there any reason why you  6 would not be able to give me accurate and  7 truthful testimony today?  8 A. No.  9 Q. And would you like to read and  10 sign your deposition?  11 MR. HANSEL: Yes.  12 MS. ISIDRO: Thank you.  13 BY MS. ISIDRO:  14 Q. You're appearing here today  15 pursuant to a notice of deposition;  16 correct?  17 A. Correct.  18 MS. ISIDRO: All right. We're  19 going to go ahead and mark that notice  20 of deposition as Exhibit Number 1.  21 (Exhibit 1 marked for  22 identification, multi-page document,  23 deposition notice for Kaliopi  24 Panagos.)  25 BY MS. ISIDRO:</p>

<p style="text-align: right;">Page 14</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 Q. Dr. Panagos, have you seen this  3 document before?  4 A. Yes.  5 Q. Okay. I'm going to ask you to  6 please turn to page 6.  7 And you see there are a number  8 of requests listed there and on the next  9 few pages as well?  10 A. Yes.  11 Q. Have you seen those requests  12 before?  13 A. Yes.  14 Q. And did you perform a search of  15 your records to locate any documents or  16 items that might be responsive to each of  17 these requests?  18 A. Yes.  19 Q. Are you aware that your counsel  20 has produced written responses and  21 objections to these requests?  22 MR. HANSEL: Object to the form.  23 A. Could you restate the question.  24 MS. ISIDRO: Could you just read  25 back the question, please.</p>	<p style="text-align: right;">Page 16</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 the responses to the requests that are  3 contained in this document, starting on  4 page 2 of the document?  5 A. Yes.  6 Q. All right. So we're going to go  7 through some of the requests, and the first  8 one is a request for your current CV.  9 Now, there was a CV that was  10 attached to your recent 2022 report;  11 correct?  12 A. Correct.  13 Q. And there is a more recent CV  14 that was produced along with these  15 responses that are marked as Exhibit Number  16 2; correct?  17 A. Correct.  18 Q. Okay.  19 MS. ISIDRO: I'm going to have  20 marked as Exhibit Number 3 the CV that  21 was produced together with the  22 responses to the requests in the  23 notice of deposition, so I understand  24 this is your 2023 CV.  25 (Exhibit 3 marked for</p>
<p style="text-align: right;">Page 15</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 (Requested portion of record  3 read.)  4 A. Yes.  5 MS. ISIDRO: And let's go ahead  6 and mark Exhibit 2.  7 (Exhibit 2 marked for  8 identification, multi-page document,  9 plaintiffs' objections/responses to  10 deposition of Kaliopi Panagos.)  11 MR. HANSEL: Just to be clear,  12 we don't represent Dr. Panagos. She's  13 an independent expert. I'm defending  14 her deposition but not as her  15 attorney.  16 BY MS. ISIDRO:  17 Q. Okay. Dr. Panagos, we've marked  18 as Exhibit 2 Plaintiffs' Objections and  19 Responses to the Notice of Deposition and  20 the requests that were contained in that  21 notice.  22 Have you seen this document  23 previously before today?  24 A. Yes.  25 Q. Were you involved in preparing</p>	<p style="text-align: right;">Page 17</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 identification, four-page document, CV  3 of Kaliopi Panagos.)  4 BY MS. ISIDRO:  5 Q. Dr. Panagos, could you please  6 take a look at Exhibit Number 3 and just  7 confirm for me that this is your most  8 current CV?  9 A. Yes.  10 Q. Thank you.  11 MS. ISIDRO: And let's go ahead  12 and mark as Exhibit Number 4 the copy  13 of your CV that was included with your  14 2022 report in this case.  15 (Exhibit 4 marked for  16 identification, four-page document,  17 Appendix B to CV of Kaliopi Panagos.)  18 BY MS. ISIDRO:  19 Q. So, Dr. Panagos, when did you  20 update your CV from -- the one that's  21 marked as Exhibit 4 to the one that's  22 marked as Exhibit 3?  23 A. Sometime in the fourth quarter  24 of '22.  25 Q. Was there any particular reason</p>

<p style="text-align: right;">Page 18</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 why you undertook to update it at that  3 time?  4 A. Yes.  5 Q. What was the purpose of updating  6 it at that time?  7 A. To add some additional items and  8 just edit the resume -- edit the CV.  9 Q. Let's talk about some of the  10 information that is updated or different in  11 the latest version of this CV.  12 It appears that in some  13 instances you've deleted some of the  14 references to PBMs; is that correct?  15 A. No, that is not correct.  16 Q. Okay. So if you look on Exhibit  17 Number 4, do you see where it says "a  18 focused ability to empower teams to deliver  19 the highest quality in the areas of overall  20 PBM operations, clinical development and  21 client account member services"?  22 A. Yes.  23 Q. And that no longer appears in  24 your 2023 CV, Exhibit Number 3; correct?  25 A. Not in exactly the same written</p>	<p style="text-align: right;">Page 20</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 Q. So there's also not a reference  3 to operations in the Executive Overview  4 anymore; correct?  5 A. Again, that is found throughout  6 my CV in my experience and skillset.  7 Q. But not in the Executive  8 Overview in the 2023 CV?  9 A. That word, no.  10 Q. And I also see that there's a  11 slight -- there's a change to the dates of  12 your various positions at ARMSRx Pharmacy  13 Benefit Consulting?  14 A. Yes.  15 Q. Can you tell me a little bit  16 more about the reason for that change?  17 A. My responsibilities and my  18 length at the company are the same, and my  19 -- the dates were just adjusted accordingly  20 to reflect the appropriate responsibility  21 during that time frame.  22 Q. So in Exhibit 4, which is the  23 2022 CV, it says that you were in the  24 senior vice president clinical and  25 consulting role through April of 2021;</p>
<p style="text-align: right;">Page 19</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 format.  3 Q. And what I'm interpreting from  4 your response, that you believe there is  5 analogous information just not written in  6 that way; is that right?  7 A. The information is still the  8 same.  9 Q. Okay. And can you point to me  10 where the analogous information is in  11 Exhibit Number 3?  12 A. The Executive Overview is the  13 same.  14 Q. Is there still a reference to  15 PBM operations in the Executive Overview in  16 Exhibit 3?  17 A. The references to PBM are  18 throughout my CV, including my experience  19 and skillset.  20 Q. But in the Executive Overview,  21 there's no longer a mention to PBM  22 operations; correct?  23 A. Specifically, the word "PBM,"  24 no, but the overall message is the same.  25 It's applicable. That's what I do.</p>	<p style="text-align: right;">Page 21</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 correct?  3 A. Correct.  4 Q. And then in the 2023 CV, which  5 is Exhibit 3, it says that you were in the  6 senior vice president clinical and  7 consulting role until March of 2020;  8 correct?  9 A. Correct.  10 Q. So it seems to have rolled back  11 in the latest version of this CV, and so  12 I'm just trying to understand what the  13 reason for that change is, since it's a  14 change to past experience rather than  15 current experience.  16 A. No particular reason other than  17 discussions with our leadership team in  18 terms of my accurate responsibilities  19 during that time that reflected more of an  20 executive role, vice president  21 responsibilities as opposed to the SVP  22 responsibilities. My functions in the  23 company are consistent.  24 Q. So was the April 2021 date  25 inaccurate in the 2022 CV that is</p>

<p style="text-align: right;">Page 22</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 Exhibit 4?</p> <p>3 A. Could you restate that question</p> <p>4 with the dates?</p> <p>5 Q. Sure. Your 2022 CV, which is</p> <p>6 Exhibit 4, states that you were in the</p> <p>7 senior vice president clinical and</p> <p>8 consulting role through April of 2021.</p> <p>9 Is that date inaccurate, the</p> <p>10 April 2021 date?</p> <p>11 A. Yes.</p> <p>12 Q. And the accurate date is the</p> <p>13 March 2020 date that's in the 2023 CV,</p> <p>14 Exhibit 3?</p> <p>15 A. Yes.</p> <p>16 Q. Was there an official -- let me</p> <p>17 restate that.</p> <p>18 What did the process of changing</p> <p>19 your title from senior vice president to</p> <p>20 executive vice president at ARMSRx Pharmacy</p> <p>21 Benefit Consulting consist of?</p> <p>22 A. Leadership, the leadership of</p> <p>23 the organization assigning me the, you</p> <p>24 know, title of executive vice president.</p> <p>25 Q. And when did that occur?</p>	<p style="text-align: right;">Page 24</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 Q. Did you check that written</p> <p>3 confirmation at the time that you were</p> <p>4 updating your CV?</p> <p>5 A. No.</p> <p>6 Q. Was there a change to your</p> <p>7 compensation associated with the change in</p> <p>8 your title?</p> <p>9 A. No.</p> <p>10 Q. And when you testified at your</p> <p>11 deposition last year, you said that you</p> <p>12 were in the executive vice president role</p> <p>13 through 2021; correct?</p> <p>14 A. If that's what you have there.</p> <p>15 Q. If that's what it says in the</p> <p>16 transcript?</p> <p>17 A. If that's what it says in the</p> <p>18 transcript.</p> <p>19 Q. Okay. In your 2023 CV, you've</p> <p>20 also added an end date for your time on the</p> <p>21 Council of Strategic Health Advisors; is</p> <p>22 that correct?</p> <p>23 A. Yes.</p> <p>24 Q. And that end date is 2020?</p> <p>25 A. Yes.</p>
<p style="text-align: right;">Page 23</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 A. Yeah, it was in -- Exhibit 3 is</p> <p>3 really the more correct date there, March</p> <p>4 of 2020.</p> <p>5 Q. How did the process of assigning</p> <p>6 you the title of executive vice president</p> <p>7 occur?</p> <p>8 A. The leadership of our</p> <p>9 organization assigned me the role of</p> <p>10 executive vice president, so we had a</p> <p>11 discussion.</p> <p>12 Q. So it was something that</p> <p>13 occurred in a verbal discussion?</p> <p>14 A. Yes.</p> <p>15 Q. Was there an email or a letter</p> <p>16 to formalize the title change, or press</p> <p>17 release, maybe?</p> <p>18 A. No press release, and updates</p> <p>19 through the -- our internal system, but</p> <p>20 there wasn't any press release.</p> <p>21 Q. Okay. Any email or letter to</p> <p>22 you confirming the title change?</p> <p>23 A. I'd have to go check and I'm</p> <p>24 pretty sure there was a confirmation</p> <p>25 through some written format.</p>	<p style="text-align: right;">Page 25</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 Q. Sometime in 2020?</p> <p>3 A. Yes.</p> <p>4 Q. Why the change there?</p> <p>5 A. I have -- there is potential for</p> <p>6 doing some work with that organization</p> <p>7 again, and so I'm just keeping that open so</p> <p>8 there really isn't an end date.</p> <p>9 Q. Okay.</p> <p>10 A. And that -- that's why it</p> <p>11 appears the way it does.</p> <p>12 Q. So, but you've added the end</p> <p>13 date now; right? Your newer CV, Exhibit 3,</p> <p>14 has the end date, whereas your prior CV,</p> <p>15 Exhibit 4, does not have the end date.</p> <p>16 A. That's an error.</p> <p>17 Q. So that end date should not have</p> <p>18 been added?</p> <p>19 A. Correct.</p> <p>20 Q. Okay. You say there's the</p> <p>21 potential for additional work with that</p> <p>22 organization; is that correct?</p> <p>23 A. They reach out, they've reached</p> <p>24 out with some requests. None of -- you</p> <p>25 know, so I think -- yes.</p>



<p style="text-align: right;">Page 26</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 Q. Are you doing anything with them</p> <p>3 currently?</p> <p>4 A. No.</p> <p>5 Q. When was the last time you did</p> <p>6 anything with them?</p> <p>7 A. I do not recall the exact dates</p> <p>8 at this time.</p> <p>9 Q. Did you do anything with them in</p> <p>10 2021?</p> <p>11 A. I would have to check the dates,</p> <p>12 honestly.</p> <p>13 Q. So you don't remember one way or</p> <p>14 the other whether you did anything with</p> <p>15 them in 2021?</p> <p>16 A. I would like to check the dates.</p> <p>17 Q. Okay.</p> <p>18 A. I wouldn't speculate.</p> <p>19 Q. Do you remember one way or the</p> <p>20 other whether you did anything with them in</p> <p>21 2022?</p> <p>22 A. Same response. I would check</p> <p>23 the dates.</p> <p>24 Q. Okay. Turning to the</p> <p>25 "Education" section of your current CV,</p>	<p style="text-align: right;">Page 28</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 MS. ISIDRO: I'll rephrase.</p> <p>3 BY MS. ISIDRO:</p> <p>4 Q. You said that you have not kept</p> <p>5 up with what is required --</p> <p>6 A. Right.</p> <p>7 Q. -- for that.</p> <p>8 At what point did those</p> <p>9 requirements lapse for you?</p> <p>10 MR. HANSEL: Object to the form.</p> <p>11 A. The license as a whole was no</p> <p>12 longer valuable or pertinent or applicable</p> <p>13 if I was not in the role at Broadreach</p> <p>14 Medical Resources. So while I had the</p> <p>15 license, it was not really pertinent or</p> <p>16 applicable.</p> <p>17 Q. When did the license lapse?</p> <p>18 A. I'd have to check the dates.</p> <p>19 Q. Did it lapse in 2022?</p> <p>20 A. I'd have to check the dates.</p> <p>21 Q. When was the last time you</p> <p>22 renewed that license?</p> <p>23 A. I do not recall.</p> <p>24 Q. Okay. Going to the</p> <p>25 "Professional Organizations" section of</p>
<p style="text-align: right;">Page 27</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 Exhibit 3, you no longer list the New York</p> <p>3 State Department of Financial Services</p> <p>4 Independent Adjuster License Producer.</p> <p>5 A. Right.</p> <p>6 Q. Under "Education."</p> <p>7 A. Uh-huh.</p> <p>8 Q. What was the reason for removing</p> <p>9 that from your CV?</p> <p>10 A. The New York State Independent</p> <p>11 Adjuster License was obtained during my</p> <p>12 time with Broadreach Medical Resources for</p> <p>13 purposes of use while at that organization.</p> <p>14 I have not kept up with the</p> <p>15 required -- you know, whatever it is to</p> <p>16 keep that going, nor is it pertinent to the</p> <p>17 work that I do.</p> <p>18 It was pertinent at the time</p> <p>19 when I was working for Broadreach Medical</p> <p>20 Resources, so it's no longer pertinent to</p> <p>21 my education profile on my CV.</p> <p>22 Q. And at what point did your</p> <p>23 requirements lapse for that particular --</p> <p>24 for that particular organization?</p> <p>25 MR. HANSEL: Object to the form.</p>	<p style="text-align: right;">Page 29</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 your CV, in the current CV you no longer</p> <p>3 list the American Association of Consultant</p> <p>4 Pharmacists; correct?</p> <p>5 A. Correct.</p> <p>6 Q. And why is that?</p> <p>7 A. I have not -- I'm not actively</p> <p>8 involved with that organization at this</p> <p>9 time.</p> <p>10 Q. When was the last time that you</p> <p>11 were actively involved with them?</p> <p>12 A. At the time of my -- where I</p> <p>13 listed them at my previous CV, it was</p> <p>14 active.</p> <p>15 Q. So in 2022 it was active?</p> <p>16 A. Partially, within that time</p> <p>17 frame.</p> <p>18 Q. So meaning for at least part of</p> <p>19 the year of 2022?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. And then you've added</p> <p>22 back in the "Skills and Activities" section</p> <p>23 in your current CV, which was not in the</p> <p>24 2022 CV that was attached to your latest</p> <p>25 report; correct?</p>

<p style="text-align: right;">Page 30</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 A. Yes.  3 Q. But that "Skills and Activities"  4 section was in your earlier CV that was  5 attached to your 2021 report.  6 Would it be helpful to see that  7 earlier CV?  8 A. Is it -- well, yeah.  9 MS. ISIDRO: We can go ahead and  10 mark that as Exhibit Number 5.  11 (Exhibit 5 marked for  12 identification, multi-page document,  13 Appendix A to CV of Kaliopi Panagos.)  14 BY MS. ISIDRO:  15 Q. Okay. So we've marked as  16 Exhibit 5 the CV that was attached to your  17 2021 report in this litigation.  18 A. Okay.  19 Q. And you see that there is the  20 "Skills and Activities" section in that CV,  21 which is Exhibit 5; correct?  22 A. Correct.  23 Q. What was the reason for dropping  24 that section from the 2022 CV that is  25 Exhibit 4?</p>	<p style="text-align: right;">Page 32</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 Q. And when you put together this  3 "Skills and Activities" section of your CV,  4 what did you do to generate that or add  5 that to your 2023 CV?  6 A. What did I do in terms of how  7 did I put it together?  8 Q. Uh-huh.  9 A. I just used Microsoft Word to  10 update and, you know -- or it's not an  11 update here -- each section, so.  12 Q. Did you type it up anew? Did  13 you copy and paste it from somewhere?  14 A. No, I did not type it up anew.  15 It was updated and edited from  16 the version that was existing before.  17 Q. So that version must have been  18 something other than what we have as  19 Exhibit 4, since Exhibit 4 doesn't have  20 that section; right?  21 MR. HANSEL: Object to the form.  22 A. I update my CV, as most  23 professionals do, on a regular basis. And  24 so I try to keep up with it, up to date as  25 frequently as I can, among my other</p>
<p style="text-align: right;">Page 31</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 A. It should be there. There's no  3 -- no reason, so -- skill and activities  4 are the same.  5 Q. So it was just inadvertently not  6 included in the 2022 CV?  7 A. Apparently.  8 Q. Now, in your 2021 CV, Exhibit 5,  9 the second item under "Technology and  10 Business" section of "Skills and  11 Activities" is "PBM Operations Management."  12 Do you see that?  13 A. Yes.  14 Q. That's not listed in your 2023  15 CV, Exhibit 3, is it?  16 A. Okay, yes.  17 Q. So why was that not included on  18 the 2023 CV?  19 A. That's in error. It should be  20 there also. Nothing has changed. All of  21 the skills and activities are as, you know,  22 as they were, so...  23 Q. Did you update this CV yourself  24 or did someone do it for you?  25 A. Myself, so...</p>	<p style="text-align: right;">Page 33</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 responsibilities.  3 So I updated from a version that  4 I previously had.  5 Q. Okay.  6 A. The best I could.  7 Q. Okay. But you would agree that  8 that version can't be the same version that  9 we're looking at as Exhibit 4 because  10 Exhibit 4 doesn't contain the "Skills and  11 Activities" section.  12 MR. HANSEL: Object to the form.  13 A. You could infer that.  14 Q. And you wouldn't have any reason  15 to disagree with that; right?  16 A. To disagree with what exactly?  17 Q. The fact that Exhibit 4 doesn't  18 contain the "Skills and Activities"  19 section, but the version that you were  20 working off of did.  21 A. Correct.  22 Q. And so you also don't know why  23 "PBM Operations Management" isn't listed on  24 the version of your CV that's Exhibit 3?  25 MR. HANSEL: Object to the form.</p>

<p style="text-align: right;">Page 34</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 A. The "why" would be in my -- I'm</p> <p>3 updating it. Clearly, you know, an error</p> <p>4 on my part in updating. I'm the only one</p> <p>5 updating it, so...</p> <p>6 Q. You've added under "Skills and</p> <p>7 Activities" Google Project Management</p> <p>8 courses; correct?</p> <p>9 A. Correct.</p> <p>10 Q. And what did those Google</p> <p>11 Project Management courses entail?</p> <p>12 A. They were online courses around</p> <p>13 project management functions and skills and</p> <p>14 training. That kind of thing, so...</p> <p>15 Q. Was it general project</p> <p>16 management or geared toward any particular</p> <p>17 industry or industries?</p> <p>18 A. Not geared to any particular</p> <p>19 industry. Just general project management</p> <p>20 applicable to any industry.</p> <p>21 Q. And if we can turn to the</p> <p>22 "Communication" heading under "Skills and</p> <p>23 Activities" in Exhibit 3.</p> <p>24 You state that you were</p> <p>25 presenter at PBMI health underwriters</p>	<p style="text-align: right;">Page 36</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 Q. August of '22.</p> <p>3 What was the topic of that</p> <p>4 presentation?</p> <p>5 A. The topic of the presentation</p> <p>6 was PBM strategies, specialty strategies,</p> <p>7 trend management.</p> <p>8 Q. And can you tell me briefly what</p> <p>9 that entailed?</p> <p>10 A. Sure. I presented on strategies</p> <p>11 around management of drug management,</p> <p>12 formulary management, utilization</p> <p>13 management programs, patient assistance</p> <p>14 programs, drug co-pay programs, overall</p> <p>15 management of employer, pharmacy benefits</p> <p>16 strategies on a whole, a discussion around</p> <p>17 biosimilar medications, brand/generic</p> <p>18 strategies, again, on the formulary, yeah.</p> <p>19 Q. Was that an individual</p> <p>20 presentation or did you have any</p> <p>21 co-presenters with you?</p> <p>22 A. No co-presenters.</p> <p>23 Q. Where did that presentation take</p> <p>24 place?</p> <p>25 A. In Florida.</p>
<p style="text-align: right;">Page 35</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 organizations and other industry</p> <p>3 conferences; correct?</p> <p>4 A. Correct.</p> <p>5 Q. And if we look at Exhibit 5</p> <p>6 under "Communications," you mention</p> <p>7 specifically "PBMI Opioid Epidemic."</p> <p>8 A. Right.</p> <p>9 Q. As well as health underwriters</p> <p>10 organizations; correct?</p> <p>11 A. Correct, correct.</p> <p>12 Q. So the reference to "PBMI,"</p> <p>13 rather than specifying "opioid epidemic"</p> <p>14 now is general.</p> <p>15 Have there been additional</p> <p>16 presentations for PBMI other than the</p> <p>17 opioid epidemic presentation that you gave?</p> <p>18 A. Yes.</p> <p>19 Q. And how many additional</p> <p>20 presentations to PBMI?</p> <p>21 A. One.</p> <p>22 Q. Just one?</p> <p>23 A. Just one.</p> <p>24 Q. And when did that occur?</p> <p>25 A. August of '22.</p>	<p style="text-align: right;">Page 37</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 Q. Did you have any written</p> <p>3 materials or PowerPoint or anything like</p> <p>4 that that went along with it?</p> <p>5 A. I did.</p> <p>6 Q. PowerPoint, specifically?</p> <p>7 A. Yes.</p> <p>8 Q. Any other written materials?</p> <p>9 A. No.</p> <p>10 Q. And do you still have a copy of</p> <p>11 that PowerPoint?</p> <p>12 A. Yes.</p> <p>13 Q. Was that presentation recorded?</p> <p>14 A. I believe it was.</p> <p>15 Q. Do you know where that recording</p> <p>16 may be available?</p> <p>17 A. No.</p> <p>18 Q. Now, you also mention other</p> <p>19 industry conferences in your latest CV.</p> <p>20 What other industry conferences</p> <p>21 besides PBMI and health underwriters</p> <p>22 organizations have you presented at?</p> <p>23 A. I attended AMCP conference and</p> <p>24 it wasn't a formal presentation, but we had</p> <p>25 discussions there.</p>

<p style="text-align: right;">Page 38</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 My organization has a conference</p> <p>3 or meeting, my company, and so I'll speak</p> <p>4 there as well, and I will be speaking at a</p> <p>5 conference next month also.</p> <p>6 Q. Okay. So what does "AMCP" stand</p> <p>7 for?</p> <p>8 A. Academy of Managed Care</p> <p>9 Pharmacy.</p> <p>10 Q. And when did that conference</p> <p>11 take place?</p> <p>12 A. March of '22, I believe.</p> <p>13 Q. Where was it?</p> <p>14 A. Chicago.</p> <p>15 Q. And you said you're speaking</p> <p>16 next month at a different conference.</p> <p>17 A. Correct.</p> <p>18 Q. What conference is that going to</p> <p>19 be?</p> <p>20 A. The Abarca Forward conference.</p> <p>21 Q. I'm sorry, "Abarca"?</p> <p>22 A. Abarca Forward conference.</p> <p>23 Q. What does Abarca stand for? Is</p> <p>24 that an acronym?</p> <p>25 A. No, Abarca is a PBM.</p>	<p style="text-align: right;">Page 40</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 A. No.</p> <p>3 Q. Any new professional experience</p> <p>4 since your last deposition?</p> <p>5 A. Could you be more specific?</p> <p>6 Q. Your CV indicates you've</p> <p>7 continued in your role at AristaRx, correct</p> <p>8 -- excuse me -- at ARMSRx; correct?</p> <p>9 A. Correct.</p> <p>10 Q. And you continue at AristaRx</p> <p>11 Wellness; correct?</p> <p>12 A. Correct.</p> <p>13 Q. Have you held any other</p> <p>14 positions or had any other additional</p> <p>15 professional experience since the date of</p> <p>16 your last deposition in this case?</p> <p>17 A. I have not held any other</p> <p>18 positions.</p> <p>19 Q. And have you had any other</p> <p>20 professional experience beyond what you've</p> <p>21 had with those two organizations since your</p> <p>22 last deposition?</p> <p>23 MR. HANSEL: Object to the form.</p> <p>24 A. I have not held any other</p> <p>25 positions with any other organizations</p>
<p style="text-align: right;">Page 39</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 Q. And where is that conference</p> <p>3 taking place?</p> <p>4 A. Puerto Rico.</p> <p>5 Q. So any others besides the March</p> <p>6 '22 Academy of Managed Care Pharmacy</p> <p>7 conference and the Abarca conference that's</p> <p>8 coming up next month?</p> <p>9 MR. HANSEL: Object to the form.</p> <p>10 A. My company has a conference or</p> <p>11 industry meeting for which I spoke at, and</p> <p>12 other than that, no.</p> <p>13 Q. And when you say your company,</p> <p>14 are you referring to AristaRx or to ARMSRx?</p> <p>15 A. I'm referring to ARMSRx.</p> <p>16 Q. Dr. Panagos, you have not</p> <p>17 received any new degrees since your last</p> <p>18 deposition in this case; correct?</p> <p>19 A. Correct.</p> <p>20 Q. Have you received any other</p> <p>21 formal education since your last deposition</p> <p>22 in this case?</p> <p>23 A. No.</p> <p>24 Q. Any new teaching positions since</p> <p>25 your last deposition?</p>	<p style="text-align: right;">Page 41</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 other than those two.</p> <p>3 Q. So outside of the professional</p> <p>4 experiences that you've had at ARMSRx and</p> <p>5 AristaRx, have you had any professional</p> <p>6 experience since your last deposition?</p> <p>7 MR. HANSEL: Object to the form.</p> <p>8 A. My license and profession</p> <p>9 requires ongoing continuing education which</p> <p>10 I regard as professional experience, so</p> <p>11 that's an ongoing process.</p> <p>12 Q. Okay. What continuing education</p> <p>13 have you had since your last deposition in</p> <p>14 this case?</p> <p>15 A. Several, varied and continuing</p> <p>16 education is an ongoing process</p> <p>17 requirement, so...</p> <p>18 Q. Has your continuing education</p> <p>19 since your last deposition in this case</p> <p>20 taken place in person, online?</p> <p>21 A. A combination of both.</p> <p>22 Q. How many times in the last year</p> <p>23 have you had continuing education?</p> <p>24 A. Many. I don't have exact</p> <p>25 number, but it's, like I said, ongoing,</p>

<p style="text-align: right;">Page 42</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 so...  3 Q. Is it something you do monthly,  4 quarterly?  5 A. Quarterly.  6 Q. When was the last one?  7 A. Last quarter.  8 Q. Q4 2022?  9 A. Q4 2022.  10 Q. Was that one in person or  11 online?  12 A. Online.  13 Q. And how many hours was that?  14 A. 1.5, I believe.  15 Q. What were the topics or topic?  16 A. Biosimilars.  17 Q. And what about in Q3 2022?  18 A. I don't recall.  19 Q. When was the last one you did in  20 person?  21 A. AMCP.  22 Q. So that was the March 2022?  23 A. Correct.  24 Q. And what were the topics --  25 excuse me -- how many hours was the</p>	<p style="text-align: right;">Page 44</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 A. No.  3 Q. Have you engaged in any academic  4 or professional research relating to  5 valsartan or valsartan-containing drugs  6 outside of this litigation?  7 A. No.  8 Q. Have you engaged in any academic  9 or professional research regarding  10 bioequivalence?  11 A. No.  12 Q. And you're still a member of the  13 American College of Healthcare Executives;  14 correct?  15 A. Yes.  16 Q. And the Academy of Managed Care  17 Pharmacy?  18 A. Yes.  19 Q. And Women Leading Healthcare  20 member?  21 A. Yes.  22 Q. And you're still a member of  23 Healthcare Businesswomen's Association?  24 A. Yes.  25 Q. And also the American Society of</p>
<p style="text-align: right;">Page 43</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 continuing education?  3 A. Total credits there, I really  4 don't recall. There were about ten  5 credits, somewhere there.  6 Q. And what were the topics?  7 A. Varied. Therapeutic conditions,  8 PBM trends and -- a combination of clinical  9 and PBM topics, so...  10 Q. Do you submit your credits to an  11 accrediting organization?  12 A. Yes.  13 Q. What's that organization?  14 A. CP, I believe it's called.  15 Q. So any continuing education that  16 you would have done, you would have  17 submitted those credits?  18 A. Yes.  19 Q. Okay. Since your last  20 deposition in this case, have you served on  21 any P&amp;T committees?  22 A. No.  23 Q. Have you written or contributed  24 to any publications since your last  25 deposition in this case?</p>	<p style="text-align: right;">Page 45</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 Health-System Pharmacists?  3 A. Yes.  4 Q. Is that a complete list?  5 Are there any other associations  6 that you're currently a member of?  7 A. American Pharmacists  8 Association.  9 Q. And from what year to what year  10 have you been a member of the American  11 Pharmacists Association?  12 A. I just renewed recently so -- I  13 guess you could say '23. I just renewed  14 recently membership there.  15 Q. I'm sorry, I just want to make  16 sure I understood.  17 You just joined recently or you  18 just renewed recently?  19 A. Renewed.  20 Q. Renewed recently.  21 And when did you first join that  22 association?  23 A. When I was in pharmacy school a  24 long time ago.  25 Q. You don't list that organization</p>

<p style="text-align: right;">Page 46</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 on your CV; correct?  3 A. Correct.  4 Q. Why is that?  5 A. It was dormant. I hadn't  6 renewed, so...  7 Q. Okay. How long had it been  8 dormant?  9 A. Sometime after I graduated  10 pharmacy school. I did not engage or  11 partake, participate with that organization  12 as much as I did during my time in pharmacy  13 school, so sometime after that.  14 Q. Since your last deposition in  15 this case, have you had any licenses  16 suspended?  17 A. No.  18 Q. Have you had any punishment or  19 sanction from a professional board?  20 A. No.  21 Q. And have you done any -- have  22 you worked for or consulted with FDA?  23 A. No.  24 Q. Have you had any other  25 experience or training since your prior</p>	<p style="text-align: right;">Page 48</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 calculate. It's not my primary source of  3 income.  4 Q. And do you have any legal  5 consulting income aside from this  6 litigation?  7 A. No.  8 Q. Did you bring any documents with  9 you today for purposes of this deposition?  10 A. No.  11 Q. Did you bring any documents with  12 you that are responsive to the requests in  13 the notice of deposition?  14 A. No.  15 Q. Do you keep a file in this case,  16 a file of documents?  17 A. Yes.  18 Q. Where do you keep that file?  19 A. On my computer.  20 Q. Do you keep any handwritten  21 notes relating to this case?  22 A. I have some handwritten notes.  23 Q. And where do you keep those?  24 A. In my office.  25 Q. In Florida?</p>
<p style="text-align: right;">Page 47</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 deposition in this case that is relevant to  3 the opinions you are rendering in this case  4 and that we have not already discussed  5 today?  6 A. No.  7 Q. Since your prior deposition in  8 this case, have you spoken with any  9 plaintiff in this litigation?  10 A. No.  11 Q. Have you been a party to any  12 lawsuit?  13 A. No.  14 Q. Have you been retained as an  15 expert witness in any litigations other  16 than this one?  17 A. No.  18 Q. Have you done any consulting  19 work for any pharmaceutical or medical  20 device company?  21 A. No.  22 Q. Dr. Panagos, currently what  23 percent of your income is generated through  24 legal consulting?  25 A. A small percent. I'd have to</p>	<p style="text-align: right;">Page 49</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 A. My remote office is in New York.  3 Q. Okay. So when you refer to your  4 office, you're not referring to the  5 professional address in Florida. You're  6 referring to --  7 A. Correct.  8 Q. -- your remote office in New  9 York. Is that in your home in New York?  10 A. That is correct.  11 MS. ISIDRO: Let's go ahead and  12 mark as Exhibit Number 6 a copy of  13 your 2022 report in this case.  14 (Exhibit 6 marked for  15 identification, multi-page document,  16 Expert Report of Kaliopi Panagos.)  17 BY MS. ISIDRO:  18 Q. Dr. Panagos, could you just  19 please take a look at Exhibit 6 for me and  20 confirm that this is a copy of your most  21 recent report in this litigation, along  22 with the appendix -- I'm sorry -- the  23 Exhibit A and Appendix A to your latest  24 report.  25 A. Yes.</p>



<p style="text-align: right;">Page 50</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 Q. Okay. If you could turn to the</p> <p>3 Appendix A, please.</p> <p>4 If you go to page 23 of the</p> <p>5 report, the page after that is your Exhibit</p> <p>6 A and the page after that is the start of</p> <p>7 your Appendix A.</p> <p>8 A. Exhibit A, okay.</p> <p>9 Q. And then the page after that is</p> <p>10 Appendix A; correct?</p> <p>11 A. Yeah.</p> <p>12 Q. Yeah. So if you could just take</p> <p>13 a look at that Appendix A for me and</p> <p>14 confirm that this is the full list of the</p> <p>15 materials that you reviewed in forming your</p> <p>16 opinions in connection with the attached</p> <p>17 2022 report, Exhibit 6.</p> <p>18 A. Okay, yes.</p> <p>19 Q. That's accurate?</p> <p>20 A. Yes.</p> <p>21 Q. And so this would also contain</p> <p>22 all materials that you've relied on in</p> <p>23 forming your opinions that you expressed in</p> <p>24 your 2022 report; correct?</p> <p>25 A. In addition to my education and</p>	<p style="text-align: right;">Page 52</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 mark Exhibit Number 7.</p> <p>3 (Exhibit 7 marked for</p> <p>4 identification, four-page document,</p> <p>5 Kaliopi Panagos invoices.)</p> <p>6 MR. HANSEL: Excuse me, we've</p> <p>7 been going about an hour.</p> <p>8 Would this be an okay time to</p> <p>9 take a short break?</p> <p>10 MS. ISIDRO: Sure.</p> <p>11 THE VIDEOGRAPHER: This will end</p> <p>12 Media Unit 1.</p> <p>13 Going off the record at 11:21.</p> <p>14 (A recess was taken.)</p> <p>15 THE VIDEOGRAPHER: We are back</p> <p>16 on the record at 11:37 a.m.</p> <p>17 This will begin Media Unit 2.</p> <p>18 BY MS. ISIDRO:</p> <p>19 Q. Now, Dr. Panagos, we had just</p> <p>20 marked Exhibit 7 prior to the break.</p> <p>21 Do you have a copy of that in</p> <p>22 front of you?</p> <p>23 A. Yes.</p> <p>24 Q. And does Exhibit 7 contain all</p> <p>25 of your invoices in this litigation to</p>
<p style="text-align: right;">Page 51</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 background and experience, correct.</p> <p>3 Q. You haven't reviewed any medical</p> <p>4 records pertaining to the plaintiffs in</p> <p>5 this litigation; correct?</p> <p>6 A. Correct.</p> <p>7 MR. HANSEL: Object to the form.</p> <p>8 BY MS. ISIDRO:</p> <p>9 Q. How much are you charging per</p> <p>10 hour for your work in this litigation?</p> <p>11 A. \$375.</p> <p>12 Q. And you're being reimbursed for</p> <p>13 deposition or travel expenses?</p> <p>14 A. Correct.</p> <p>15 Q. How do you keep your time on</p> <p>16 this case?</p> <p>17 A. In an Excel tracking</p> <p>18 spreadsheet.</p> <p>19 Q. On your computer?</p> <p>20 A. On my computer.</p> <p>21 Q. How much have you charged to</p> <p>22 date for your work on this case?</p> <p>23 A. The invoice is included -- the</p> <p>24 invoice that was submitted is included.</p> <p>25 MS. ISIDRO: Let's go ahead and</p>	<p style="text-align: right;">Page 53</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 date?</p> <p>3 A. What was submitted.</p> <p>4 Q. What do you mean "what was</p> <p>5 submitted"?</p> <p>6 A. It consists of the invoices I</p> <p>7 submitted thus far.</p> <p>8 Q. So these are all of the invoices</p> <p>9 that you've submitted to plaintiffs'</p> <p>10 counsel in this litigation thus far?</p> <p>11 A. Thus far.</p> <p>12 Q. Okay. And it looks like it's --</p> <p>13 I can't tell if it's three or four separate</p> <p>14 exhibits -- sorry -- three or four separate</p> <p>15 invoices.</p> <p>16 A. Yeah, it looks like four pages</p> <p>17 here.</p> <p>18 Q. Four pages, but what I'm asking</p> <p>19 is, are they four separate exhibits --</p> <p>20 excuse me, I keep misspeaking.</p> <p>21 Are they four separate invoices?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. And did these each get</p> <p>24 submitted separately to plaintiffs'</p> <p>25 counsel?</p>

<p style="text-align: right;">Page 54</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 A. The dates are listed here, but</p> <p>3 it was submitted -- they were all submitted</p> <p>4 -- when you mean "separately," what do you</p> <p>5 mean?</p> <p>6 Q. So let's actually talk about the</p> <p>7 dates for a second.</p> <p>8 So the dates that are listed</p> <p>9 here are the dates of the work performed;</p> <p>10 correct?</p> <p>11 A. Correct.</p> <p>12 Q. And the invoices themselves</p> <p>13 don't have dates, correct, like the date of</p> <p>14 the invoice as opposed to date of the work</p> <p>15 performed.</p> <p>16 A. Correct.</p> <p>17 Q. So because the invoices don't</p> <p>18 each have their own date, what I'm asking</p> <p>19 is whether each of these was submitted</p> <p>20 separately to plaintiffs' counsel or were</p> <p>21 these submitted all at once?</p> <p>22 A. They were submitted all at once.</p> <p>23 Q. When were these submitted to</p> <p>24 plaintiffs' counsel?</p> <p>25 A. It was in '22, sometime after</p>	<p style="text-align: right;">Page 56</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 doing any work on this case, not actively?</p> <p>3 A. No -- I'll go back and check the</p> <p>4 dates but there are -- I've tracked</p> <p>5 everything and there's -- no, there's some</p> <p>6 items from Q2 there as well.</p> <p>7 Q. Okay. And what about the rest</p> <p>8 of Q1, after January 23rd of 2022?</p> <p>9 A. Again, I'll go back and check my</p> <p>10 records, but there may be -- there may be a</p> <p>11 couple things there, but I have to check my</p> <p>12 records on -- as I track them.</p> <p>13 Q. Okay. But as far as working on</p> <p>14 the report that's marked as Exhibit 6, that</p> <p>15 didn't start until sometime in Q3 of 2022?</p> <p>16 A. About Q3. Again, I can check</p> <p>17 the dates if you're interested precisely,</p> <p>18 but about that, you could say.</p> <p>19 Q. You have the ability to check</p> <p>20 those today?</p> <p>21 MR. HANSEL: I object to that.</p> <p>22 She's not here to do research</p> <p>23 today.</p> <p>24 MS. ISIDRO: Well --</p> <p>25 MR. HANSEL: She's here to</p>
<p style="text-align: right;">Page 55</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 the last deposition. I don't have the</p> <p>3 exact date.</p> <p>4 Q. Okay. And it looks like the</p> <p>5 last date of work that is reflected on</p> <p>6 these invoices is January 23rd of 2022;</p> <p>7 correct?</p> <p>8 A. That is correct.</p> <p>9 Q. Have you submitted any invoices</p> <p>10 -- let me rephrase that.</p> <p>11 You haven't submitted any</p> <p>12 invoices to plaintiffs' counsel other than</p> <p>13 these four pages that we have marked as</p> <p>14 Exhibit 7; correct?</p> <p>15 A. That is correct.</p> <p>16 Q. How much time have you spent</p> <p>17 working on this litigation that is not</p> <p>18 reflected on these invoices?</p> <p>19 A. Somewhere about a hundred hours.</p> <p>20 Q. When did you begin working on</p> <p>21 the report that's marked as Exhibit 6?</p> <p>22 A. About Q3 -- yeah, Q3 of '22</p> <p>23 sometime.</p> <p>24 Q. So between January 23rd of 2022</p> <p>25 and sometime in Q3 of 2022, you weren't</p>	<p style="text-align: right;">Page 57</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 testify about what she knows.</p> <p>3 MS. ISIDRO: The amount of time</p> <p>4 that she's spent on her report is</p> <p>5 relevant and it's part of what was</p> <p>6 requested in the requests associated</p> <p>7 with the deposition notice.</p> <p>8 So if she has access to the</p> <p>9 information today, she has offered to</p> <p>10 look at the information. If she has</p> <p>11 access to the information today it</p> <p>12 would be helpful.</p> <p>13 I'm just trying to get a sense</p> <p>14 of whether she does have access to</p> <p>15 that information today or not.</p> <p>16 THE WITNESS: No, I do not.</p> <p>17 BY MS. ISIDRO:</p> <p>18 Q. Dr. Panagos, your invoices</p> <p>19 reflect two different rates in the heading,</p> <p>20 one with the notation "T" and the other one</p> <p>21 "NT."</p> <p>22 Can you tell me the difference</p> <p>23 between those two, please?</p> <p>24 A. Nontestifying and testifying.</p> <p>25 Q. So the rate you mentioned</p>



<p style="text-align: right;">Page 58</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 earlier, 375 per hour, is for your  3 nontestifying work; correct?  4 A. Correct.  5 Q. And your testifying work is 400  6 an hour?  7 A. Yes, that's correct.  8 Q. Have the invoices in Exhibit 7  9 been paid?  10 A. Yes.  11 Q. Who do you send your invoices  12 to?  13 A. Preti Flaherty.  14 Q. Any particular individual?  15 A. Greg Hansel.  16 THE VIDEOGRAPHER: Going off the  17 record at 11:46.  18 (Technical difficulty.)  19 THE VIDEOGRAPHER: We're going  20 back on the record now.  21 We are back on the record at  22 11:46.  23 BY MS. ISIDRO:  24 Q. Dr. Panagos, do you have any new  25 engagement letters in connection with this</p>	<p style="text-align: right;">Page 60</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 on the report began sometime in or about Q3  3 of 2022; correct?  4 A. That is correct.  5 Q. And you also testified that  6 there had been some additional work in  7 between which presumably is included in  8 those one hundred hours; correct?  9 A. Yes.  10 Q. So my question to you is, about  11 how many hours did you spend working on  12 your report that is marked as Exhibit 6?  13 A. All of the work I've done since  14 this last invoice is applicable to my  15 report that I submitted.  16 So all of the hours I've given  17 you and the question you just asked are  18 applicable to this report.  19 Q. Okay. So when you testified  20 earlier that you began working on this  21 report on or about Q3 of 2022, what are you  22 referring to?  23 A. Any of the research that's  24 necessary, materials to read, updates,  25 anything pertaining to the report.</p>
<p style="text-align: right;">Page 59</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 case?  3 A. I do not.  4 Q. And has anyone assisted you in  5 doing research or gathering information in  6 connection with your opinions in the report  7 that's marked as Exhibit 6?  8 A. No.  9 Q. Other than plaintiffs' counsel,  10 have you spoken to anyone about this  11 litigation?  12 A. No.  13 Q. How much time did you spend  14 working on the report that's marked as  15 Exhibit 6?  16 MR. HANSEL: Object to the form.  17 Asked and answered.  18 A. I answered earlier. My  19 estimated hours that I'm tracking in my  20 Excel spreadsheet on the work I've done  21 since the last invoice that was submitted.  22 Q. Correct, and you testified about  23 a hundred additional hours; right?  24 A. That is what I said.  25 Q. And you testified that your work</p>	<p style="text-align: right;">Page 61</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 Q. Did you review the opinions of  3 any other experts in this litigation or  4 proffered experts in this litigation in  5 connection with preparing your report?  6 A. No.  7 Q. Did plaintiffs' counsel provide  8 any facts or assumptions for your  9 consideration that you used in your  10 opinions?  11 A. They're all listed in the  12 appendix.  13 Q. You're referring to documents;  14 correct?  15 A. Correct.  16 Q. Outside of what's listed in  17 Appendix A, did plaintiffs' counsel provide  18 any facts or assumption for your  19 consideration that you used in your  20 opinions?  21 A. Everything I used for my report  22 is listed in the Appendix A.  23 Q. Okay. Were there any materials  24 that you requested in preparing your report  25 that's marked as Exhibit 6 that were not</p>

<p style="text-align: right;">Page 62</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 provided to you?  3 A. No.  4 Q. Did you review any company  5 witness depositions in preparing your  6 report that's marked as Exhibit 6?  7 A. No.  8 Q. And have you communicated with  9 anyone at any of the defendant companies  10 since your prior deposition in this case?  11 A. No.  12 Q. All right, Dr. Panagos, I'm  13 going to ask you some questions about your  14 report that's marked as Exhibit 6, but  15 before we get started on that, is there  16 anything that you need to revise or correct  17 in the report?  18 I ask only because sometimes,  19 you know, when we depose-- when we depose  20 someone they may have reviewed their  21 materials in advance and may have some  22 thoughts that they want to revise or  23 clarify.  24 So as you sit here right now, is  25 there anything that you would like to</p>	<p style="text-align: right;">Page 64</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 A. Could you clarify what you mean  3 by "opinions expressed prior to paragraph  4 13"?  5 Q. Sure. In paragraphs 1 through  6 12, are you expressing any of your opinions  7 in connection with this litigation?  8 A. No.  9 Q. Okay. Doctor, in paragraph 13  10 you state that: "Diovan and Exforge are a  11 class of medications known as angiotensin  12 receptor binders or ARBs for short."  13 Is that correct?  14 A. Correct.  15 Q. Can you describe what an ARB is?  16 A. Angiotensin receptor binder is  17 used for antihypertensive treatment either  18 as monotherapy or in combination with other  19 therapies. It's used to lower blood  20 pressure.  21 Q. And how does Exforge differ from  22 Diovan?  23 A. They're in the same family of  24 medications but they differ in their  25 ingredients.</p>
<p style="text-align: right;">Page 63</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 revise or clarify in your report?  3 A. Not at this time.  4 Q. And, Doctor, the first page  5 and-a-half of your report is essentially a  6 summary of your background and  7 qualifications, correct, Section II?  8 A. Yes.  9 Q. Is there anything in that  10 section that we haven't already discussed  11 but you feel we should discuss as pertinent  12 to the bases for your qualifications --  13 excuse me -- for your opinions?  14 MR. HANSEL: Object to the form.  15 A. No.  16 Q. And can you confirm for me, Dr.  17 Panagos, that there are no opinions  18 expressed in any of the paragraphs prior to  19 paragraph 13 in your report?  20 MR. HANSEL: Object to the form.  21 A. Restate the question, please.  22 MS. ISIDRO: Can you read back  23 the question, please.  24 (Requested portion of record  25 read.)</p>	<p style="text-align: right;">Page 65</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 Q. Are those their active  3 ingredients?  4 A. Active ingredients, and perhaps  5 even the inactive ingredients.  6 Q. What are the differences, if  7 any, in the active ingredients between  8 Exforge and Diovan?  9 A. That was outside the scope of  10 this report so I would have to review that.  11 Q. Do both Diovan and Exforge  12 contain valsartan?  13 MR. MESTRE: Object to the form.  14 MR. HANSEL: Object to the form.  15 You can answer.  16 THE WITNESS: Oh, okay.  17 A. Yes.  18 Q. Does Diovan contain any other  19 active ingredient that you're aware of?  20 MR. HANSEL: Object to the form.  21 A. None that I'm aware of.  22 Q. Does Exforge contain other  23 active ingredients that you're aware of?  24 MR. HANSEL: Object to the form.  25 A. None that I'm aware of.</p>

<p style="text-align: right;">Page 66</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 Q. You state in your report that</p> <p>3 the FDA approved Diovan on August 3rd of</p> <p>4 2005; correct?</p> <p>5 A. Correct.</p> <p>6 Q. What was the source of that</p> <p>7 information?</p> <p>8 A. The FDA website.</p> <p>9 Q. Is it a particular website</p> <p>10 identified on your Appendix A?</p> <p>11 A. It should be there, yes.</p> <p>12 Q. Can you locate it for me,</p> <p>13 please.</p> <p>14 A. There are several references to</p> <p>15 the USFDA sites on page 4.</p> <p>16 Q. Is the first one that you're</p> <p>17 referring to the second item that's listed</p> <p>18 on page 4 of Appendix A?</p> <p>19 A. Correct.</p> <p>20 Q. And that's a page involving ANDA</p> <p>21 forms and submission requirements?</p> <p>22 A. It begins there, yes.</p> <p>23 Q. And the next one is a specific</p> <p>24 section of the CFR?</p> <p>25 A. Correct.</p>	<p style="text-align: right;">Page 68</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 among the references.</p> <p>3 So if you're looking for which</p> <p>4 one specific, it is within the references,</p> <p>5 and, again, it's public information on</p> <p>6 approval dates of drugs.</p> <p>7 Q. But as you sit here today, are</p> <p>8 you able to identify a particular reference</p> <p>9 which contains that approval date listed on</p> <p>10 your Appendix A?</p> <p>11 A. It is among the references</p> <p>12 listed in Appendix A, public information</p> <p>13 found on the USFDA site, among other sites.</p> <p>14 Q. But as you sit here today,</p> <p>15 you're not able to identify where in</p> <p>16 Appendix A, which reference in Appendix A?</p> <p>17 MR. HANSEL: Objection.</p> <p>18 Asked and answered.</p> <p>19 A. It is found in several of the</p> <p>20 references here, so, you know...</p> <p>21 Q. Can you point me to any of the</p> <p>22 references that contain that approval date?</p> <p>23 A. I'd have to review them and</p> <p>24 point you to it, but it is there.</p> <p>25 Q. When you say you'd have to</p>
<p style="text-align: right;">Page 67</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 Q. And the next one is a page</p> <p>3 discussing development and approval</p> <p>4 process?</p> <p>5 A. Correct.</p> <p>6 Q. And that one is not actually an</p> <p>7 FDA page but rather a Mayo Clinic page that</p> <p>8 discusses the FDA process?</p> <p>9 A. Right.</p> <p>10 Q. The next one is an FDA page</p> <p>11 regarding drug recalls?</p> <p>12 A. Right.</p> <p>13 Q. The next one is an FDA page</p> <p>14 discussing nitrosamines.</p> <p>15 It says "FDA statement on the</p> <p>16 Agency's list of known nitrosamine-free</p> <p>17 valsartan and ARB class medicines."</p> <p>18 A. That's what it says.</p> <p>19 Q. So far are any of these the ones</p> <p>20 that contained the information regarding</p> <p>21 the approval date for Diovan?</p> <p>22 A. Information on the approval</p> <p>23 dates of medications are public</p> <p>24 information. They could be found in</p> <p>25 several of my references in Appendix A</p>	<p style="text-align: right;">Page 69</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 review them, you mean review the list or</p> <p>3 review the references themselves?</p> <p>4 A. I have reviewed the list and I</p> <p>5 would look through -- if you're looking for</p> <p>6 the dates that are public information on</p> <p>7 drug approvals, I would review the</p> <p>8 references to find that within the</p> <p>9 references that are already listed in</p> <p>10 Appendix A.</p> <p>11 Q. Okay.</p> <p>12 A. With that information.</p> <p>13 Q. But, Doctor, as you sit here</p> <p>14 today, are you able to point to any</p> <p>15 reference on Appendix A that contains the</p> <p>16 approval date for Diovan?</p> <p>17 A. I already answered the question.</p> <p>18 Q. It's a yes-or-no question.</p> <p>19 A. No.</p> <p>20 Q. And as you sit here today, are</p> <p>21 you able to identify a reference on</p> <p>22 Appendix A that includes the approval date</p> <p>23 for Exforge?</p> <p>24 A. Same response, no.</p> <p>25 Q. In paragraph 14 of your report,</p>

<p style="text-align: right;">Page 70</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 you state that:  3 "Valsartan and  4 valsartan-containing drugs, or VCDs for  5 short, are generics for the Reference  6 Listed Drugs."  7 Correct?  8 A. Correct.  9 Q. When you use the term "VCDs" in  10 your report, are you referring to both  11 valsartan and valsartan-containing drugs?  12 A. Valsartan and  13 valsartan-containing drugs, yes.  14 Q. So what do you mean when you say  15 that the "VCDs are generics for the  16 Reference Listed Drugs"?  17 A. They are the generic for the  18 Reference Listed Drug, or RLD drugs, brand  19 name drugs.  20 Q. In paragraph 15 you state:  21 "On March 30, 2015, the FDA  22 approved Torrent's and Teva's Abbreviated  23 New Drug Application (ANDA), and on  24 February 8, 2016, the FDA approved ZHP's  25 ANDA."</p>	<p style="text-align: right;">Page 72</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 time for the specified ANDAs.  3 Can you identify which sources  4 in Appendix A contained the information  5 regarding the approval dates?  6 A. They're listed in Appendix --  7 Appendix A, sorry, page 1 -- it's in the  8 references in Appendix A.  9 Q. As you sit here today, can you  10 identify any reference on Appendix A that  11 contains the approval date for the Torrent  12 ANDA?  13 A. Yes, they're in Appendix A.  14 Q. Can you point to any particular  15 reference on Appendix A that contains that  16 approval date?  17 A. Any reference that's referring  18 to the ANDA would contain that information.  19 Q. Okay.  20 A. And they're throughout Appendix  21 A.  22 Q. Which reference refers to the  23 Torrent ANDA?  24 MR. HANSEL: Object to the form.  25 Asked and answered.</p>
<p style="text-align: right;">Page 71</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 Can you tell us what an "ANDA"  3 is?  4 A. An ANDA is an Abbreviated New  5 Drug Application submitted by manufacturers  6 for consideration of approval of their drug  7 product by the FDA.  8 Q. Is it for a specific type of  9 drug product?  10 A. A manufacturer will submit an  11 ANDA specific to their -- the drug they are  12 seeking approval for.  13 Q. Would a Reference Listed Drug be  14 approved pursuant to an ANDA?  15 A. A Reference Listed Drug would be  16 subject to an NDA, New Drug Application.  17 Q. And so how does an ANDA differ  18 from an NDA?  19 A. An ANDA is an Abbreviated New  20 Drug Application and they -- the ANDA is  21 looking at sameness to the Reference Listed  22 Drug that the manufacturer is seeking  23 approval for.  24 Q. Dr. Panagos, paragraph 15 again  25 references certain approval dates, this</p>	<p style="text-align: right;">Page 73</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 A. Page 2 at the top is referring  3 to the Torrent ANDA.  4 Q. And can you identify a reference  5 on Exhibit -- excuse me -- Appendix A that  6 contains the approval date for the ZHP  7 ANDA?  8 A. Page 4 has a reference, but,  9 again, there are several references here to  10 the ANDAs and the manufacturers, so among  11 others, there is a reference to page 4.  12 Q. I'm sorry, which one on page 4?  13 A. Third from the bottom, among  14 other references in Appendix A.  15 Q. Is there any reference in  16 Appendix A that refers specifically to the  17 approval of the ZHP ANDA?  18 A. There is.  19 Q. And which one is that?  20 A. Page 4, third from the bottom,  21 fifth from the bottom, second from the top,  22 among other places, so...  23 Q. Okay. Doctor, the third from  24 the bottom on page 4, that's a warning  25 letter. That's not an approval letter for</p>

<p style="text-align: right;">Page 74</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 an ANDA; correct?  3 A. That is the warning letter,  4 correct. But the -- so the approval dates  5 would be contained within that letter,  6 so...  7 Q. And the fifth from the bottom,  8 that's "Listed Drugs By ANDA Reference  9 Standard List," and it's your testimony --  10 A. It consists of the dates.  11 Q. -- that that contains the dates  12 of approval?  13 A. It is a list of the ANDAs.  14 Q. And it includes their dates of  15 approval?  16 A. As I recall.  17 Q. And the second from the top,  18 that's a page that discusses forms and  19 submission requirements; correct?  20 A. That is correct.  21 Q. And that wouldn't contain  22 approval dates for specific ANDAs; correct?  23 A. As I -- as I recall, I'd have to  24 -- right, it states here what the reference  25 is.</p>	<p style="text-align: right;">Page 76</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 "NDMA is classified as a group 2A  3 carcinogen."  4 What do you rely on for that  5 statement?  6 A. The FDA -- FDA information  7 regarding -- the FDA information regarding  8 this drug and the recall.  9 Q. What do you mean by "FDA  10 information"?  11 A. The information posted on the  12 FDA's site regarding the contaminants, NDEA  13 and NDMA, as probable human carcinogens.  14 That information is also found  15 in the International Agency for Research on  16 Cancer on the classification of NDMA as a  17 probable human carcinogen.  18 Q. And that's the reference that's  19 cited in footnote 1 of your report?  20 A. Yes, right.  21 Q. In paragraph 18 you state that:  22 "Animal studies have found that  23 NDMA caused liver and lung cancer, as well  24 as other cancers."  25 What do you rely on for that</p>
<p style="text-align: right;">Page 75</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 Q. Dr. Panagos, in paragraph 16 you  3 state that "In July 2018 and  4 September 2018, respectively, the FDA  5 announced a voluntary recall of VCDs due to  6 contaminants NDEA and NDMA."  7 What do you understand the term  8 "contaminants" to mean?  9 A. A substance or product that was  10 not in the original product and harmful to  11 humans.  12 Q. What do you rely on for that  13 definition?  14 A. My education and background,  15 profession as a pharmacist.  16 Q. And in providing that  17 definition, what do you mean by "the  18 original product"?  19 A. The Reference Listed Drug  20 product or the brand product.  21 Q. Do you know whether the FDA  22 defines the term "contaminants"?  23 A. I'm not sure if the FDA defines  24 as a definition.  25 Q. In paragraph 17 you state that</p>	<p style="text-align: right;">Page 77</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 information?  3 A. Same reference.  4 Q. The IARC information?  5 A. Yes.  6 Q. Anything else?  7 A. My background and education and  8 experience as a clinical pharmacist.  9 Q. What aspect of your background,  10 education and experience covers the studies  11 relating to -- the animal studies relating  12 to NDMA and cancer?  13 A. I do know that NDMA is a -- and  14 NDEA for that matter are human carcinogens,  15 probable human carcinogens.  16 That's, you know, well-known in  17 my profession and in the work that I do and  18 it's my responsibility as a pharmacist to  19 know that.  20 So all of my education,  21 experience and background would be  22 applicable here.  23 Q. So in paragraph 18, aside from  24 the IARC information and what you've just  25 testified to regarding your background,</p>

<p style="text-align: right;">Page 78</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 education and experience, is there anything  3 else that you're relying on?  4 A. All of it is listed in Appendix  5 A.  6 Q. You're relying on every single  7 reference in Appendix A for paragraph 18?  8 A. I'm relying to the references in  9 Appendix A, one or more or all.  10 Q. As you sit here today, can you  11 identify the specific references in  12 Appendix A that support paragraph 18?  13 A. The first one on page 1.  14 Q. So that's IARC. We've already  15 discussed that one.  16 Any others?  17 A. There's reference on page 2 --  18 five from the top -- fifth down from the  19 top.  20 Q. That's the Drug Watch page on  21 NDMA?  22 A. Yes.  23 Q. Any others?  24 A. That's it at this time.  25 Q. Have you personally reviewed any</p>	<p style="text-align: right;">Page 80</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 paragraphs discuss background on TPPs; is  3 that correct?  4 A. That's correct.  5 Q. And what do you rely on for the  6 information in those paragraphs?  7 A. My experience and my education  8 and background.  9 Q. Anything else?  10 A. Primarily -- primarily that and  11 the references in Appendix A.  12 Q. Which particular references in  13 Appendix A?  14 A. Primarily from my experience. I  15 -- at this point, I'm not sure which are  16 referenced precisely in Appendix A, but I'm  17 confident with the information that I have  18 there.  19 Q. In paragraph 20 you also state  20 that it is your understanding "that the  21 Court will conduct a trial which will  22 involve purchases paid for by SummaCare,  23 Inc. and EmblemHealth, both of which are  24 TPPs."  25 A. I am aware.</p>
<p style="text-align: right;">Page 79</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 of the animal studies?  3 A. No.  4 Q. In paragraph 19 you state that:  5 "NDEA, similar to NDMA, is a  6 probable human carcinogen."  7 Correct?  8 A. That is correct.  9 Q. And what do you rely on for that  10 statement?  11 A. It says "as per IARC  12 classification."  13 Q. So are you relying on anything  14 other than IARC for that statement?  15 A. My education, background,  16 experience and the references we just  17 talked about.  18 Q. The Drug Watch page on NDMA?  19 A. The references we just talked  20 about in Appendix A, yes.  21 Q. So that would include the Drug  22 Watch page on NDMA?  23 A. Yes.  24 Q. Looking at paragraphs 20 to 23  25 of your report, Dr. Panagos, these</p>	<p style="text-align: right;">Page 81</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 Q. And what did you rely on for  3 that statement?  4 A. Counsel.  5 Q. Did you review any materials  6 relating specifically to SummaCare?  7 A. Those are listed in Appendix A.  8 Q. Did you review any deposition  9 testimony of any representative of  10 SummaCare?  11 A. No.  12 Q. Did you review any deposition  13 testimony of any representative of  14 EmblemHealth?  15 A. No.  16 Q. If there were such depositions,  17 would those be relevant to your opinions?  18 A. No.  19 Q. Which generic VCDs were on those  20 two entities' formularies?  21 A. The ones that were paid for by  22 those -- by those organizations, so they're  23 -- the generics of those -- of the drugs  24 were on the formulary and the claims that  25 were paid for demonstrate that they were on</p>



<p style="text-align: right;">Page 82</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 the formulary.  3 Q. Did you look at which generic  4 VCDs were paid for by SummaCare?  5 A. I did review claims. I did take  6 a look at claims.  7 Q. And so do you know which generic  8 VCDs were paid for by SummaCare?  9 A. They're within the claims that  10 -- that I reviewed.  11 Q. And that's which reference or  12 references on Appendix A?  13 A. References to the formularies  14 and claims are found on pages 2 and 3.  15 Q. So which ones on 2 and 3 relate  16 to which generic VCDs were paid for by  17 SummaCare?  18 A. Page 2, where it says "Emblem,"  19 that's referring to the formularies.  20 Q. That's for Emblem, though. Not  21 SummaCare; correct?  22 A. Oh, page 3 is referring to  23 SummaCare. Two references on page 3, yeah.  24 Q. Is that the -- which two  25 references?</p>	<p style="text-align: right;">Page 84</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 insureds' purchases."  3 Is that correct?  4 A. Correct.  5 Q. Do these -- do SummaCare and  6 Emblem participate in Medicare Part D?  7 A. They could -- they do.  8 Q. And are you familiar with the  9 structure in funding of Medicare Part D  10 plans?  11 A. Yes.  12 Q. Are those plans directly  13 subsidized by the federal government?  14 MR. MESTRE: Object to the form.  15 A. They're government plans.  16 Q. And they're designed to minimize  17 or eliminate risks and economic costs borne  18 by Medicare Part D sponsors; correct?  19 MR. HANSEL: Object to the form.  20 A. I'm not here to render an  21 opinion on what Medicare Part D functions  22 are.  23 I am -- what I stated in 21 is  24 that SummaCare and Emblem, the payors, they  25 made the payments for those claims.</p>
<p style="text-align: right;">Page 83</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 A. The ones that say "SummaCare."  3 Q. The provider manual and the  4 formularies?  5 A. Yes.  6 Q. In paragraph 20 you go on to say  7 that: "These TPPs, as with most TPPs, both  8 included generic VCDs on their drug  9 formularies and reimbursed for purchases of  10 these VCDs (intended for personal or  11 household use)."  12 Correct?  13 A. Right.  14 Q. What did you rely on for that  15 statement?  16 A. The claims that I looked at, all  17 the information in Appendix A, and the  18 references in Appendix A of the claims.  19 Q. And these are the references  20 that we just discussed in Appendix A?  21 A. Correct.  22 Q. In paragraph 21 you state that:  23 "SummaCare and Emblem are the  24 payors ultimately responsible, or at risk,  25 for payments associated with their</p>	<p style="text-align: right;">Page 85</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 Q. Have you factored in any  3 subsidies received from the federal  4 government in connection with Medicare Part  5 D with respect to any of those payments?  6 MR. HANSEL: Object to the form.  7 A. No.  8 Q. In paragraph 22 you state that:  9 "TPPs manage claims processing,  10 provider networks, utilization reviews,  11 formulary, and membership."  12 Correct?  13 A. Correct.  14 Q. Is all of that done directly by  15 TPPs?  16 A. It could be.  17 Q. What role do TPAs play in that  18 process?  19 A. They may have some  20 administrative processes -- administrative  21 processes, you know, around these  22 functions, and they function in an  23 administrative capacity.  24 Q. What do you mean by "an  25 administrative capacity"?</p>

<p style="text-align: right;">Page 86</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 A. They are not at risk.</p> <p>3 Q. Does that mean financial risk or</p> <p>4 are you referring to other types of risk?</p> <p>5 A. Financial risk.</p> <p>6 Q. Looking at the next section</p> <p>7 starting at paragraph 24 of your report,</p> <p>8 this describes background information on</p> <p>9 PBMs; is that correct?</p> <p>10 A. Yes.</p> <p>11 Q. What did you rely on to form the</p> <p>12 opinions -- what did you rely on for</p> <p>13 purposes of the statements in paragraph 24</p> <p>14 through 27 of your report?</p> <p>15 A. My experience, knowledge,</p> <p>16 background, education. That's what I do.</p> <p>17 Q. Did you rely on any particular</p> <p>18 references in Appendix A for purposes of</p> <p>19 paragraphs 24 through 27 in your report?</p> <p>20 A. There are references to PBMs</p> <p>21 among the references in Appendix A, but I</p> <p>22 know through my experience and education</p> <p>23 and background what a PBM function is.</p> <p>24 Q. So am I understanding correctly</p> <p>25 that while there may be some information</p>	<p style="text-align: right;">Page 88</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 Q. In paragraph 27 of your report,</p> <p>3 you state that it is your understanding</p> <p>4 that Express Scripts was Emblem's PBM and</p> <p>5 MedImpact was SummaCare's; correct?</p> <p>6 A. Correct.</p> <p>7 Q. What is your basis for that</p> <p>8 statement?</p> <p>9 A. Counsel.</p> <p>10 Q. Anything else?</p> <p>11 A. No.</p> <p>12 Q. And in that same paragraph you</p> <p>13 state specific dates during which Express</p> <p>14 Scripts provided PBM services to Emblem and</p> <p>15 during which MedImpact provided PBM</p> <p>16 services to SummaCare.</p> <p>17 Is that also based on</p> <p>18 representations of counsel?</p> <p>19 A. Yes.</p> <p>20 Q. And when you say "counsel,"</p> <p>21 you're referring to plaintiffs' counsel;</p> <p>22 correct?</p> <p>23 A. Correct.</p> <p>24 Q. Paragraphs 28 through 38 provide</p> <p>25 background information on prescription drug</p>
<p style="text-align: right;">Page 87</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 relating to PBMs in the references listed</p> <p>3 in Appendix A, paragraphs 24 through 27 are</p> <p>4 really based on your background, experience</p> <p>5 and education?</p> <p>6 A. Yeah, yes.</p> <p>7 Q. What specific aspects of your</p> <p>8 background, experience and education form</p> <p>9 paragraphs 24 through 27?</p> <p>10 A. My over 20 years in managed care</p> <p>11 experience that I have.</p> <p>12 Q. Have you ever worked for a PBM?</p> <p>13 A. Yes.</p> <p>14 Q. In what capacity?</p> <p>15 A. I was the clinical director.</p> <p>16 Q. And can you identify that for me</p> <p>17 on your 2023 CV, Exhibit 3?</p> <p>18 A. SmithRx.</p> <p>19 Q. And that was a position you held</p> <p>20 during calendar year 2018?</p> <p>21 A. Yes.</p> <p>22 Q. From what month to what month?</p> <p>23 A. January through December,</p> <p>24 November, something like that. Before the</p> <p>25 holidays.</p>	<p style="text-align: right;">Page 89</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 formularies; correct?</p> <p>3 A. Correct.</p> <p>4 Q. What did you rely on for the</p> <p>5 information contained in those paragraphs,</p> <p>6 28 through 38?</p> <p>7 A. Primarily my experience, my</p> <p>8 education and background, and there are</p> <p>9 footnotes among those sections that you</p> <p>10 pointed out which I reference at the</p> <p>11 bottom, in addition to any references</p> <p>12 within Appendix A.</p> <p>13 Q. Are there particular references</p> <p>14 in Appendix A that support your paragraphs</p> <p>15 28 -- excuse me -- 28 through 38?</p> <p>16 A. Paragraphs listed on page 1,</p> <p>17 American Journal of Managed Care, AMCP</p> <p>18 Formulary Management, Caremark, Formulary</p> <p>19 Development further down, another reference</p> <p>20 to the Journal of Managed Care on page 2.</p> <p>21 At this time, those are the</p> <p>22 references.</p> <p>23 Q. In paragraph 30 you state that</p> <p>24 both EmblemHealth and SummaCare have their</p> <p>25 own internal P&amp;T committees; correct?</p>



<p style="text-align: right;">Page 90</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 A. Correct, to my knowledge.</p> <p>3 Q. What is your basis for that</p> <p>4 statement?</p> <p>5 A. Counsel.</p> <p>6 Q. Anything besides counsel?</p> <p>7 A. No.</p> <p>8 Q. Have you ever worked for</p> <p>9 EmblemHealth?</p> <p>10 A. No.</p> <p>11 Q. Have you ever worked for</p> <p>12 SummaCare?</p> <p>13 A. No.</p> <p>14 Q. Did you review any contracts</p> <p>15 between Express Scripts and Emblem?</p> <p>16 A. No.</p> <p>17 Q. Looking at the next section of</p> <p>18 your report, paragraphs 39 through 46, you</p> <p>19 have a section entitled "ANDA Approval";</p> <p>20 correct?</p> <p>21 A. Correct.</p> <p>22 Q. What is the basis for the</p> <p>23 information contained in paragraphs 39</p> <p>24 through 46 of your report?</p> <p>25 A. Those are found in Appendix A.</p>	<p style="text-align: right;">Page 92</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 A. No.</p> <p>3 Q. Have you ever been involved with</p> <p>4 submitting an ANDA?</p> <p>5 A. No.</p> <p>6 Q. Have you ever been involved with</p> <p>7 the review and approval process for an</p> <p>8 ANDA?</p> <p>9 A. No.</p> <p>10 Q. Have you ever been involved with</p> <p>11 inclusion -- with the decision to include a</p> <p>12 drug in the Orange Book?</p> <p>13 A. No.</p> <p>14 Q. In paragraph 35 you state:</p> <p>15 "The P&amp;T committee is required</p> <p>16 to base formulary decisions on scientific</p> <p>17 evidence, standards of practice,</p> <p>18 peer-reviewed medical literature, accepted</p> <p>19 clinical practice guidelines and other</p> <p>20 appropriate information."</p> <p>21 A. That is correct.</p> <p>22 Q. What is your basis for that</p> <p>23 statement?</p> <p>24 A. My education, experience and</p> <p>25 background understanding how P&amp;T committees</p>
<p style="text-align: right;">Page 91</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 Any reference that has "ANDA" is</p> <p>3 fair game for those -- for this section.</p> <p>4 Q. Do you have any experience in</p> <p>5 the ANDA approval process?</p> <p>6 A. Other than that it's required</p> <p>7 for generic drugs in order to obtain FDA</p> <p>8 approval and be included in the Orange</p> <p>9 Book, that's the experience that I have</p> <p>10 with ANDA.</p> <p>11 Q. What experience do you have with</p> <p>12 that?</p> <p>13 A. Understanding what the</p> <p>14 importance of the ANDA is as it pertains to</p> <p>15 generic drugs.</p> <p>16 Q. So in your view, the importance</p> <p>17 of the ANDA is that it is required for FDA</p> <p>18 approval and for inclusion in the Orange</p> <p>19 Book?</p> <p>20 A. It is required -- it's submitted</p> <p>21 by manufacturers to be considered for</p> <p>22 approval by the FDA and inclusion into the</p> <p>23 Orange Book.</p> <p>24 Q. Have you ever been involved with</p> <p>25 putting together an ANDA?</p>	<p style="text-align: right;">Page 93</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 work.</p> <p>3 Q. Any particular references in</p> <p>4 Appendix A that you rely on for purposes of</p> <p>5 that statement?</p> <p>6 A. "Caremark, Formulary</p> <p>7 Development" on page 1, that could be a</p> <p>8 reference. But it's what I do, it's my</p> <p>9 knowledge. I know this very well,</p> <p>10 confidently.</p> <p>11 Q. So while there may be some</p> <p>12 references in Appendix A that touch on this</p> <p>13 subject, in terms of what you're relying on</p> <p>14 for that paragraph, it's your background,</p> <p>15 education and experience?</p> <p>16 A. And the references in Appendix</p> <p>17 A, that is correct.</p> <p>18 Q. You said the Caremark, Formulary</p> <p>19 Development on page 1 could be a reference.</p> <p>20 A. Among the other references in</p> <p>21 Appendix A, and my 20-plus years and</p> <p>22 experience in managed care practice, where</p> <p>23 I know the functions of a P&amp;T committee.</p> <p>24 Q. And so my question, Dr. Panagos,</p> <p>25 is whether that -- your education,</p>

<p style="text-align: right;">Page 94</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 experience and background -- is what you're  3 relying on?  4 A. Primarily.  5 Q. What is the other appropriate  6 information that paragraph 35 refers to?  7 A. It's contingent upon the drug  8 they're reviewing.  9 Q. How so?  10 A. Whether it's a brand or generic  11 and -- it's contingent upon what the drug  12 is used for, what therapeutic category.  13 There are several factors there  14 that would be pertaining to other  15 appropriate information as with regards to  16 the specific drug in question.  17 Q. What are some examples of other  18 appropriate information?  19 A. Any relevant medical literature,  20 any studies, any -- you know, any criteria,  21 any manufacturer information pertaining to  22 that drug.  23 Q. You state in paragraph 43 that  24 the "Regulations require an ANDA to contain  25 a 'basis for ANDA submission.'"</p>	<p style="text-align: right;">Page 96</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 identification, five-page document  3 titled "Abbreviated New Drug  4 Application (ANDA) Forms and  5 Submission Requirements.")  6 BY MS. ISIDRO:  7 Q. Doctor, this is a copy of the  8 reference that's listed in footnote 6 of  9 your report; correct?  10 A. Correct.  11 Q. Can you show me where this  12 reference indicates that the supply chain  13 must be solid for approval of an ANDA, Good  14 Manufacturing Practices and inspection  15 reports are considered?  16 MR. HANSEL: Object to the form.  17 A. When an ANDA is approved by the  18 FDA to be the same, and the product is  19 approved to be the same as the Reference  20 Listed Drug product safety and  21 effectiveness, that demonstrates that it  22 has met a solid process, including Good  23 Manufacturing Practices that do not render  24 the product adulterated in any way.  25 So by virtue of the FDA</p>
<p style="text-align: right;">Page 95</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 What regulations are you  3 referring to there?  4 A. Federal regulations for ANDA  5 submission.  6 Q. Any specific federal regulations  7 for ANDA submission?  8 A. No, that's -- that's outside the  9 scope of my opinion, but there are  10 regulations for ANDA.  11 Q. In paragraph 46 you provide a  12 footnote number 6, referencing a page of  13 the FDA website; correct?  14 A. Correct.  15 Q. Does that mean that that  16 particular page provides the basis for your  17 statement that the supply chain must be  18 solid, and for approval of an ANDA, Good  19 Manufacturing Practices and inspection  20 reports are considered?  21 A. Correct.  22 MS. ISIDRO: Let's go ahead and  23 mark the next exhibit. I believe this  24 is Exhibit 8.  25 (Exhibit 8 marked for</p>	<p style="text-align: right;">Page 97</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 approval, all of those items have been  3 sufficed or met.  4 Q. And what aspect of Exhibit A  5 supports that statement?  6 MR. HANSEL: I'm going to object  7 to the form of the question.  8 Exhibit A --  9 MS. ISIDRO: Excuse me, Exhibit  10 8. I misspoke.  11 MR. HANSEL: Exhibit 8 is loaded  12 with hot links to scores of other  13 materials which are not part of the  14 exhibit.  15 A. I'll just add, that's common  16 pharmacy practice.  17 As a pharmacist, knowledge of a  18 supply chain that is producing solid, safe  19 and effective medications that -- in  20 compliance with Good Manufacturing  21 Practices is -- it's key, is pertinent, is  22 absolutely necessary. There is no  23 deviation from that.  24 Q. Doctor, you chose to include  25 specifically this link.</p>

<p style="text-align: right;">Page 98</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 A. Right.  3 Q. In footnote 6 in connection with  4 your statement in paragraph 46; correct?  5 A. Right.  6 Q. Why did you choose that  7 reference in particular for that paragraph?  8 A. As counsel already stated,  9 there's several other links to many  10 references within this reference with  11 pertinent information regarding ANDA, their  12 forms, their submission process that  13 demonstrate and support the fact that the  14 supply chain needs to be solid.  15 FDA approved product needs to be  16 safe and effective and in compliance with  17 Good Manufacturing Practice to be approved,  18 gain entry into the Orange Book and be  19 available for prescribing to humans.  20 Q. It's your testimony that you're  21 familiar with the information contained in  22 Exhibit 8; correct?  23 A. Correct.  24 Q. So what aspect of the  25 information contained here supports the</p>	<p style="text-align: right;">Page 100</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 pharmacist for way over 20 years in  3 understanding how the supply chain works  4 and what's required for a drug to be in  5 compliance with these requirements in order  6 to be available for prescribers to  7 prescribe.  8 Q. So to be clear, the statement in  9 paragraph 46 is your own words. It's not  10 something that's coming directly from the  11 reference you've cited in Exhibit 6?  12 A. That's not what I said.  13 If you go back to my statement,  14 I point out several areas within this  15 reference where regulatory requirements,  16 process, submission and references to the  17 statement would be found and supported, in  18 addition to my experience and over 20-plus  19 years in -- as a clinical pharmacist,  20 understanding how the supply chain works.  21 Q. The specific statement, though,  22 is not a direct quote from this reference;  23 correct?  24 MR. HANSEL: Objection.  25 Asked and answered.</p>
<p style="text-align: right;">Page 99</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 statement in paragraph 46?  3 You chose to include the  4 footnote for a reason. What aspect  5 supports that statement in paragraph 46?  6 MR. HANSEL: Take the time you  7 need to read it.  8 By the way, we ordered lunch and  9 I think it's here or it's going to be  10 here shortly. I'm not sure.  11 MS. ISIDRO: Thank you. I  12 appreciate that.  13 (Discussion held off the  14 record.)  15 A. There are several references  16 within this document that point to  17 regulatory resources.  18 It's throughout this document  19 that there are references to the ANDA  20 forms, review, the electronic submission  21 process, what that entails, you know, by  22 the FDA, formulation studies, summaries,  23 regulatory resources, compliance/regulatory  24 information.  25 And, again, my experience as a</p>	<p style="text-align: right;">Page 101</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 A. This report consists of my  3 opinions that I've -- outlining each  4 section here that are supported by the  5 references in Appendix A, including that  6 statement.  7 Q. Dr. Panagos, I'm not asking you  8 about support. I'm asking you whether it's  9 a direct quote, and it's not a direct  10 quote; correct?  11 A. Correct.  12 MS. ISIDRO: Let's go ahead and  13 take a break for lunch.  14 THE VIDEOGRAPHER: This will end  15 Media Unit 2.  16 Going off the record at 12:56.  17 (A recess was taken from 12:56  18 p.m. to 1:48 p.m.)  19  20  21  22  23  24  25</p>

<p style="text-align: right;">Page 102</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 A F T E R N O O N S E S S I O N  3 (Time Resumed: 1:48 p.m.)  4 KALIOPI PANAGOS, PharmD, R.Ph.,  5 having been previously duly sworn/affirmed,  6 resumed and testified as follows:  7 THE VIDEOGRAPHER: We're back on  8 the record at 1:48.  9 This will begin Media Unit 3.  10 CONTINUED EXAMINATION  11 BY MS. ISIDRO:  12 Q. Dr. Panagos, plaintiffs' counsel  13 mentioned that there's a correction that  14 you'd like to make to your earlier  15 testimony?  16 A. Yes, please.  17 Q. And what is that?  18 A. On page 2 in Section IV, when  19 referring to the class of medications known  20 as ARBs, the correction is angiotensin  21 receptor "blockers," not "binders." I'd  22 like that to be corrected. Thank you.  23 Q. Okay. And so that's a  24 correction to the language in your report  25 as well; correct?</p>	<p style="text-align: right;">Page 104</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 A. To be clear. It's referring to  3 a pharmacy plan.  4 Q. To the pharmacy benefit?  5 A. Yes.  6 Q. Okay. What is the purpose of  7 the formulary?  8 A. The purpose of a formulary is to  9 provide a listing of the covered  10 medications for members to know which  11 medications would be covered under their  12 plan and at what tier.  13 Q. Who develops the formulary?  14 A. Formularies are developed by the  15 P&amp;T committees, the respective organization  16 that is putting together the formulary.  17 The P&amp;T committee would be part  18 of the process of reviewing and deciding,  19 from a clinical merits standpoint, which  20 medications would be on the formulary,  21 would be included on the formulary.  22 Q. Are there different types of  23 formularies?  24 A. Yes.  25 Q. What are the different types of</p>
<p style="text-align: right;">Page 103</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 A. It's in the report, right.  3 So it says angiotensin receptor  4 "binders" and that should say "blockers,"  5 please. Thank you.  6 Q. "Blockers." Okay.  7 Okay, Doctor, so staying with  8 Exhibit 6, your current report in this  9 case, you say in paragraph 28 that a  10 prescription drug formulary is a list that  11 specifies what drugs are covered under a  12 medical plan and at what coverage amount;  13 correct?  14 A. That's what -- yes, that's what  15 it says.  16 Q. Would that be specifically  17 covered under the pharmacy benefit?  18 A. A prescription drug -- what I'm  19 referring there is the pharmacy benefit.  20 There are formularies that are,  21 you know, on medical and prescription side.  22 And in this case, "medical" is referring to  23 just medicine and it's referring to the  24 prescription drug formulary.  25 Q. Okay.</p>	<p style="text-align: right;">Page 105</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 formularies?  3 A. Those are specific to each  4 organization. There may be more broad or  5 more narrow in coverage, you know, include  6 more drugs or less drugs, and those are  7 particularly around the more expensive or  8 brand drugs.  9 Q. Is an open formulary one type of  10 formulary?  11 A. Yes.  12 Q. How about a closed formulary?  13 A. That's another type of  14 formulary.  15 Q. And what about a managed  16 formulary?  17 A. Those are all types of  18 formularies.  19 Q. What kinds of formularies have  20 you worked with specifically?  21 A. All of those that you mentioned  22 I have worked with and I'm familiar with.  23 Q. Did you work with all of those  24 at SmithRx?  25 A. I worked with all of those</p>

<p style="text-align: right;">Page 106</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 throughout my 20-plus years of experience  3 and with my work with various PBMs and  4 their type of formularies.  5 So it's, you know -- and at  6 SmithRx, yeah, there were open and closed  7 and managed formularies, yeah.  8 Q. Do TPPs make any changes to the  9 formularies that P&amp;T committees develop?  10 A. If the TPP is reliant on the P&amp;T  11 committee, whatever the P&amp;T committee is  12 that's representing the TPP, the P&amp;T  13 committee will make the recommendations on  14 to which medications will be included in  15 the formulary. That's part of their  16 function and it is to do that.  17 Q. And sometimes the P&amp;T committee  18 is part of the PBM?  19 A. It could be.  20 Q. And sometimes it can be directly  21 with the TPP?  22 A. It could be, yes.  23 Q. Have you reviewed any  24 information specific to the P&amp;T committees  25 that included VCDs on the formularies for</p>	<p style="text-align: right;">Page 108</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 Orange Book is used?  3 A. No, it is -- it is stated that  4 it's listed as guidance, so -- and it's  5 also what I believe, so both are true.  6 Q. Is it your testimony that the  7 FDA created the Orange Book specifically  8 with formularies in mind?  9 A. Not with specifically  10 formularies in mind, but guidance on  11 generic medications and -- and their  12 approval and option to include in  13 formularies. You know, one leads to the  14 other if it's approved and it could be  15 considered for inclusion on a formulary,  16 certainly.  17 Q. Have most states adopted laws  18 and/or regulations that encourage the  19 substitution of generic drug products?  20 A. That was outside the scope of  21 this report, but, yes, most states are --  22 are promoters of generic utilization and  23 generic drug products.  24 Q. And those laws and regulations  25 are typically promulgated by the State</p>
<p style="text-align: right;">Page 107</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 the TPPs that are involved in this  3 litigation?  4 A. Have I -- sorry, can you repeat  5 that question. Thank you.  6 (Requested portion of record  7 read.)  8 A. No.  9 Q. In paragraph 47 of your report,  10 you state that the Orange Book was created  11 "as guidance in creating formularies and to  12 regulate substitution."  13 Correct?  14 A. Correct.  15 Q. What is the basis for that  16 statement?  17 A. The basis for that statement is  18 through the FDA reference to the Orange  19 Book, in addition to my background and  20 experience with what the Orange Book is and  21 what it's intended and how it's utilized.  22 Q. In paragraph 47, are you  23 intending to convey what you believe to be  24 FDA's intention in creating the Orange Book  25 or simply to convey how you believe the</p>	<p style="text-align: right;">Page 109</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 Board of Pharmacy for the respective state;  3 correct?  4 MR. HANSEL: Object to the form.  5 Foundation.  6 A. Every state will have their  7 regulations on, you know, generic  8 medications. But that all stems from that  9 initial approval of the medication being  10 approved for even consideration of the  11 formulary, consideration for prescribing.  12 And then from there, each state will  13 determine how they wish to handle a generic  14 in terms of prescribing.  15 But that conversation would  16 never happen if a generic had not been  17 approved safe and effective for prescribing  18 through the process of an ANDA and FDA  19 approval in the Orange Book, and then, you  20 know, each state can make their regulations  21 as they see fit.  22 Q. So essentially the rating that's  23 indicated in the Orange Book indicates  24 whether a particular drug is substitutable  25 for another one; correct?</p>

<p style="text-align: right;">Page 110</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 A. Therapeutic equivalence,  3 therapeutically substitutable for the  4 Reference Listed Drug. Not another one,  5 but the original drug product.  6 Q. But there's nothing in the  7 Orange Book that regulates substitution in  8 the sense of mandating substitution in a  9 particular context?  10 A. There is no mandate, but what  11 the Orange Book is designed to do is convey  12 that the drug, the generic drug has met the  13 criteria for approval as safe and effective  14 by the FDA and can be considered for  15 inclusion on formularies or any other  16 regulations, including on the state level  17 that as each state sees fit, yes.  18 Q. But it doesn't take a position  19 as to recommending or encouraging  20 substitution?  21 MR. HANSEL: Object to the form.  22 A. When a generic is listed in the  23 Orange Book as meeting the criteria for  24 approval, identical to the original  25 product, safe and effective, that guidance</p>	<p style="text-align: right;">Page 112</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 Q. Nor does it conversely mandate  3 that particular products should be avoided?  4 A. Correct, yeah.  5 Q. And the Orange Book also  6 expressly states that while therapeutic  7 equivalence evaluations are a scientific  8 judgment based upon evidence, generic  9 substitution may involve social and  10 economic policy considerations; correct?  11 MR. HANSEL: Object to this line  12 of questioning. Reads long quotations  13 as if the witness is expected to  14 memorize verbatim a lengthy quotation.  15 It would be much preferable to  16 place an excerpt from the Orange Book  17 in front of the witness, so I object  18 to the form.  19 MS. ISIDRO: Could you read back  20 my question, please.  21 (Requested portion of record  22 read.)  23 A. When a patient is prescribed a  24 drug, there are many factors that go into  25 that decision.</p>
<p style="text-align: right;">Page 111</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 is affirmative that that drug is safe to  3 use, effective to the original product, and  4 that could be considered safe and effective  5 as the regular product was.  6 So it is pretty substantial  7 guidance that -- well-regarded across the  8 industry, respected and looked to as the  9 authoritative source for that type of  10 information so that generic drugs could be  11 considered for patients to use.  12 Q. But it would be up to the  13 individual states to adopt laws and/or  14 regulations that encouraged substitution of  15 drug products that are available?  16 A. States will have their  17 regulations as would, you know, PBMs could  18 have -- states will have their regulations,  19 yes, to answer your question.  20 Q. In fact, the Orange Book states  21 expressly that it does not mandate the drug  22 products that are purchased, subscribed,  23 dispensed or substituted for one another;  24 correct?  25 A. Right, they're without mandate.</p>	<p style="text-align: right;">Page 113</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 What the Orange Book does very  3 definitively is provide the guidance that  4 the generic drug has met the criteria for  5 approval by the FDA as safe and effective,  6 very simply, and that that drug could then  7 be considered for inclusion on a formulary,  8 to prescribe to a patient, safe and  9 effective for use to the original drug  10 product, very simply.  11 MS. ISIDRO: Let's go ahead and  12 mark the next exhibit.  13 (Exhibit 9 marked for  14 identification, multi-page document  15 titled "Orange Book Preface.")  16 MS. ISIDRO: I believe we're up  17 to Exhibit 9, correct?  18 MR. COATES: Yes.  19 BY MS. ISIDRO:  20 Q. Doctor, if you could take a look  21 at Exhibit 9. This is the Orange Book  22 preface; correct?  23 A. Yes.  24 Q. If you can turn to Section 1.5  25 preface.</p>



<p style="text-align: right;">Page 114</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 A. Yes.</p> <p>3 Q. And if you look at the fifth</p> <p>4 line under that section, the sentence that</p> <p>5 starts at the end of that line, can you</p> <p>6 read that sentence, please, out loud.</p> <p>7 A. The sentence that begins with</p> <p>8 "therapeutic"?</p> <p>9 Q. Correct.</p> <p>10 A. "Therapeutic equivalence</p> <p>11 evaluations are a scientific judgment based</p> <p>12 upon evidence, while generic substitution</p> <p>13 may involve social and economic policy</p> <p>14 administered by the states, for example,</p> <p>15 reducing the cost of drugs to consumers."</p> <p>16 Q. Thank you.</p> <p>17 Turning back to your latest</p> <p>18 report in this litigation, in paragraph 50</p> <p>19 you state that: "Generic drug</p> <p>20 manufacturers are permitted to avoid the</p> <p>21 expensive and lengthy New Drug Application</p> <p>22 or NDA process by filing an ANDA when</p> <p>23 generic drug contains the same active</p> <p>24 ingredient, root of administration,</p> <p>25 therapeutic equivalence and other</p>	<p style="text-align: right;">Page 116</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 Therapeutic equivalence is the important</p> <p>3 factor here.</p> <p>4 Q. In paragraph 53 of your current</p> <p>5 2022 report, you state:</p> <p>6 "P&amp;T committees will only</p> <p>7 consider adding a generic drug to their</p> <p>8 formulary if it is listed in the Orange</p> <p>9 Book and the Orange Book indicates the</p> <p>10 generic drug is the same as the RLD."</p> <p>11 What do you mean that the Orange</p> <p>12 Book indicates that the generic drug is the</p> <p>13 same as the RLD?</p> <p>14 A. If the drug is listed in the</p> <p>15 Orange Book, it designates that it is the</p> <p>16 same -- same in safety and effectiveness as</p> <p>17 the original or the RLD product and can be</p> <p>18 considered for inclusion to the formulary.</p> <p>19 Q. So when you say "the Orange Book</p> <p>20 indicates the generic drug is the same as</p> <p>21 the RLD," is that a reference to the</p> <p>22 therapeutic equivalence rating?</p> <p>23 A. Yes.</p> <p>24 Q. And you go on to say in</p> <p>25 paragraph 53: "As such, the Orange Book is</p>
<p style="text-align: right;">Page 115</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 characteristics as the brand version."</p> <p>3 A. Right.</p> <p>4 Q. You had a very similar sentence</p> <p>5 in your 2021 report in this litigation;</p> <p>6 correct?</p> <p>7 A. Correct.</p> <p>8 Q. But in that 2021 report, you</p> <p>9 stated "bioequivalence" rather than</p> <p>10 "therapeutic equivalence"; correct?</p> <p>11 A. As I recall, yes.</p> <p>12 Q. Why the change from</p> <p>13 "bioequivalence" to "therapeutic</p> <p>14 equivalence" in this report?</p> <p>15 A. Therapeutic equivalence is the</p> <p>16 more accurate and correct reference when</p> <p>17 you're talking about generic substitution.</p> <p>18 While bioequivalence is a</p> <p>19 component of that, therapeutic equivalence</p> <p>20 is the overarching value of -- important</p> <p>21 value above all.</p> <p>22 So it has to be therapeutically</p> <p>23 equivalent, safe, effective, and that is</p> <p>24 how it's referred to in the Orange Book so</p> <p>25 I wanted to be accurate in that statement.</p>	<p style="text-align: right;">Page 117</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 an essential part of their decision-making</p> <p>3 process."</p> <p>4 When you say "their</p> <p>5 decision-making process," are you talking</p> <p>6 about the P&amp;T committees?</p> <p>7 A. Yes.</p> <p>8 Q. What is your basis for that</p> <p>9 statement?</p> <p>10 A. My many years of experience and</p> <p>11 my communication and collaboration, what</p> <p>12 have you, with how P&amp;T committees work,</p> <p>13 PBMs, their processes and how formulary</p> <p>14 decisions are made, yes.</p> <p>15 Q. You've never personally served</p> <p>16 on a P&amp;T committee; correct?</p> <p>17 A. Correct.</p> <p>18 Q. And you haven't reviewed any</p> <p>19 materials that indicate how the particular</p> <p>20 P&amp;T committees of the TPPs in this</p> <p>21 litigation made their decisions; correct?</p> <p>22 A. Correct.</p> <p>23 Q. In paragraph 54C, you have an</p> <p>24 equation; correct?</p> <p>25 A. Correct.</p>

<p style="text-align: right;">Page 118</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 Q. And that's "TE equals PE plus</p> <p>3 BE"?</p> <p>4 A. Correct.</p> <p>5 Q. Where does that equation come</p> <p>6 from?</p> <p>7 A. The Orange Book.</p> <p>8 Q. That's listed specifically in</p> <p>9 the Orange Book?</p> <p>10 A. Yes. Well, this is the preface,</p> <p>11 but I know that's in there, and this is</p> <p>12 where I got that from, what that equation</p> <p>13 is there.</p> <p>14 Q. So it's not in the preface,</p> <p>15 though?</p> <p>16 A. I did not see that there.</p> <p>17 Q. So under paragraph 38 of your</p> <p>18 report, and it's actually -- it's what</p> <p>19 immediately follows, but it's on the next</p> <p>20 page.</p> <p>21 A. Yes.</p> <p>22 Q. You have a diagram titled --</p> <p>23 actually, I don't see -- I don't see a</p> <p>24 title associated with the diagram, right,</p> <p>25 it just follows paragraph 38?</p>	<p style="text-align: right;">Page 120</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 are indicated in the Orange Book?</p> <p>3 A. The approvals in the Orange Book</p> <p>4 and the determinations of therapeutic</p> <p>5 equivalence are made by the FDA.</p> <p>6 Q. In paragraph 67 of your report</p> <p>7 you state that generic manufacturers "have</p> <p>8 to comply with certain FDA requirements to</p> <p>9 receive ANDA approval"; correct?</p> <p>10 A. Correct.</p> <p>11 Q. Is safety and effectiveness part</p> <p>12 of what a generic drug manufacturer has to</p> <p>13 demonstrate in their ANDA submission?</p> <p>14 A. The generic manufacturer has to</p> <p>15 demonstrate that their product is the same</p> <p>16 as the Reference Listed Drug product, and</p> <p>17 that includes safety and effectiveness.</p> <p>18 Q. Is there an independent showing</p> <p>19 of safety and effectiveness separate from</p> <p>20 the RLD that needs to be demonstrated by</p> <p>21 the ANDA -- by the entity that's submitting</p> <p>22 the ANDA?</p> <p>23 MR. HANSEL: Object to the form.</p> <p>24 A. The -- the details of the ANDA</p> <p>25 process were outside of the scope of this</p>
<p style="text-align: right;">Page 119</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 A. Correct, yeah.</p> <p>3 Q. And is this a diagram that you</p> <p>4 created or is this something you sourced</p> <p>5 from somewhere?</p> <p>6 A. I sourced and it should be in</p> <p>7 Appendix A, and it's a general flow of P&amp;T</p> <p>8 committees' process, just to illustrate on,</p> <p>9 you know, a broad scope, how a P&amp;T</p> <p>10 committee would -- would work.</p> <p>11 Q. Is it footnote 5 on the prior</p> <p>12 page? Is that where this diagram comes</p> <p>13 from?</p> <p>14 A. Just checking...</p> <p>15 That's what it says, yes.</p> <p>16 Q. The last line of the diagram</p> <p>17 mentions "relevant stakeholders."</p> <p>18 What is your interpretation of</p> <p>19 who the relevant stakeholders would be?</p> <p>20 A. Whomever is electing coverage of</p> <p>21 that particular formulary, whatever group</p> <p>22 that would be, they would be the relevant</p> <p>23 stakeholders here.</p> <p>24 Q. Dr. Panagos, who makes the</p> <p>25 therapeutic equivalence determinations that</p>	<p style="text-align: right;">Page 121</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 opinion, but the ANDA itself demonstrates</p> <p>3 that that generic drug -- the purpose of</p> <p>4 the ANDA is that the generic drug is</p> <p>5 meeting -- is the same as the original drug</p> <p>6 product. That's what it's for. And that</p> <p>7 includes in its effectiveness and in its</p> <p>8 safety element as well.</p> <p>9 So it is part of the process, it</p> <p>10 is a critical part of the process, and the</p> <p>11 generic manufacturers must demonstrate that</p> <p>12 to receive the approval.</p> <p>13 Q. An ANDA submission would not</p> <p>14 include, for example, new clinical trials</p> <p>15 on safety and effectiveness; correct?</p> <p>16 A. Not to my knowledge.</p> <p>17 Again, it has to meet the same</p> <p>18 -- the sameness as the Reference Listed</p> <p>19 Drug with the brand product, so it would be</p> <p>20 in conjunction with the Reference Listed</p> <p>21 Drug product. It has to demonstrate</p> <p>22 sameness there.</p> <p>23 Q. In paragraph 70 and the</p> <p>24 subparagraphs underneath it, you list</p> <p>25 multiple factors that a P&amp;T committee might</p>



<p style="text-align: right;">Page 122</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 consider in deciding to place a drug on a  3 formulary; correct?  4 A. Yes.  5 Q. And that list comes from the  6 source that you've cited in footnote 8 of  7 your report?  8 A. In addition to my own  9 experience, background, education, yes.  10 Q. And the Orange Book is  11 considered among those factors; correct?  12 A. Correct.  13 Q. In fact, in paragraph 71 you  14 specify that the Orange Book is among the  15 medical literature in FDA prescribing  16 information that P&amp;T committees consider.  17 A. Correct.  18 Q. But there are a number of other  19 sources and pieces of information that are  20 listed in paragraph 70 besides the Orange  21 Book; correct?  22 A. Yes.  23 Q. A PBM can contain multiple  24 formularies; correct?  25 A. Yes.</p>	<p style="text-align: right;">Page 124</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 A. In my sources.  3 MS. ISIDRO: I'm going to mark  4 the next exhibit. I think we're up to  5 10.  6 (Exhibit 10 marked for  7 identification, multi-page document  8 titled "AMCP Formulary Management.")  9 BY MS. ISIDRO:  10 Q. Doctor, where in -- actually,  11 let me back up for a second.  12 You have Exhibit 10 in front of  13 you; correct?  14 A. Yes.  15 Q. And is Exhibit 10 the reference  16 that you are citing in footnote 8 of your  17 report?  18 A. Yes.  19 Q. Okay. Can you point me to where  20 this source indicates that the FDA-approved  21 prescribing information and related FDA  22 information, including safety data, will  23 come from the ANDA?  24 A. As I said earlier, the  25 information is from my sources, in the</p>
<p style="text-align: right;">Page 123</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 Q. And there can be different  3 criteria for each one?  4 A. Each formulary may differ from  5 one another.  6 Q. Did you look at whether there  7 were multiple formularies for the PBMs  8 involved in this litigation?  9 A. No.  10 Q. Turning back to paragraph 70,  11 and in particular subparagraph (b), you  12 mention "FDA-approved prescribing  13 information and related FDA information,  14 including safety data" is among the  15 information that might be considered;  16 correct?  17 A. Correct.  18 Q. And there's a parenthetical  19 stating that "(this will come from the  20 ANDA, which includes the information  21 provided by the manufacturer)."  22 A. Correct.  23 Q. Was that parenthetical in the  24 source that you cited or is that your own  25 addition?</p>	<p style="text-align: right;">Page 125</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 appendix which is provided here, including  3 my experience, education and background.  4 And while that isn't explicitly  5 in this source right here that you -- in  6 Exhibit 10 that you presented, part of the  7 ANDA process includes demonstrating safety  8 and effectiveness. That is without dispute  9 and without doubt part of that process.  10 And so while it's not explicitly  11 here, as I've said earlier, my references  12 include my education, background,  13 experience and knowledge in this area, so I  14 hope that answers your question.  15 Q. So just to make sure we're  16 looking at the same thing, so on page 2 of  17 Exhibit 10, there is a bullet point list at  18 the bottom of the page; correct?  19 A. Yes, I see that.  20 Q. And that bullet point list for  21 the most part corresponds with what you  22 have listed as subparagraphs (a) through  23 (g) at the top of page 12 of your report;  24 correct?  25 A. That is correct, yes.</p>

<p style="text-align: right;">Page 126</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 Q. And the second bullet point</p> <p>3 corresponds to subparagraph (b) on page 12</p> <p>4 of your report; correct?</p> <p>5 A. Yes.</p> <p>6 Q. But the bullet point in</p> <p>7 Exhibit 10 stops at safety data, and the</p> <p>8 parenthetical that appears on page 12,</p> <p>9 subparagraph (b) of your report, is not</p> <p>10 contained in Exhibit 10; correct?</p> <p>11 A. Correct.</p> <p>12 Q. So that parenthetical was your</p> <p>13 own addition based on your background and</p> <p>14 experience?</p> <p>15 A. Right, correct, yes.</p> <p>16 Q. Doctor, looking at paragraph 73</p> <p>17 of your report, did this also come from</p> <p>18 Exhibit 10?</p> <p>19 MR. HANSEL: Object to the form.</p> <p>20 A. Page 3 of Exhibit 10 and the</p> <p>21 paragraph 1 refers to "two or more</p> <p>22 medications are determined to be clinically</p> <p>23 equivalent, then business elements will</p> <p>24 determine formulary inclusion or</p> <p>25 exclusion."</p>	<p style="text-align: right;">Page 128</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 all could be considered as a reference in</p> <p>3 any of these statements.</p> <p>4 Q. But, again --</p> <p>5 A. If you're looking for the little</p> <p>6 footnote and it's not there, but it is</p> <p>7 here, so the information is here and it's</p> <p>8 the same as what's listed here.</p> <p>9 So we're talking the same thing.</p> <p>10 It's the same -- the statement is the same.</p> <p>11 Q. So when you say it's not here</p> <p>12 but it is here, are you saying it's not in</p> <p>13 paragraph 73 but it is in paragraph 70?</p> <p>14 A. If you're looking for the</p> <p>15 footnote.</p> <p>16 Q. Correct.</p> <p>17 A. And the footnote is not there</p> <p>18 but the reference is in my Appendix A.</p> <p>19 Q. Right.</p> <p>20 A. You provided Exhibit 10 as one</p> <p>21 of my references, and I pointed out that in</p> <p>22 page 3 of that reference that information</p> <p>23 could be found.</p> <p>24 Q. And your Appendix A is a list of</p> <p>25 materials reviewed; correct?</p>
<p style="text-align: right;">Page 127</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 Q. Okay. It's almost verbatim the</p> <p>3 same sentence that's in paragraph 73 of</p> <p>4 your report; correct?</p> <p>5 A. Yes.</p> <p>6 Q. But that source is not</p> <p>7 attributed in paragraph 73?</p> <p>8 MR. HANSEL: Object to the form.</p> <p>9 A. All of my sources that I used to</p> <p>10 produce this report are in the appendix,</p> <p>11 and all of them utilized to produce this</p> <p>12 report, so the reference is there.</p> <p>13 Q. But unlike in paragraph 70, you</p> <p>14 don't have a footnote in 73 indicating that</p> <p>15 this language is coming directly from this</p> <p>16 particular source that we've marked as</p> <p>17 Exhibit 10 rather than in your own words.</p> <p>18 MR. HANSEL: Object to the form.</p> <p>19 A. Clearly the reference is there,</p> <p>20 so...</p> <p>21 Q. The footnote?</p> <p>22 A. No, the information is in my</p> <p>23 references, so...</p> <p>24 As I said before, everything in</p> <p>25 my report is referenced in the appendix and</p>	<p style="text-align: right;">Page 129</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 MR. HANSEL: I object to this</p> <p>3 line of questioning.</p> <p>4 Is this like a tenure hearing</p> <p>5 where a professor is being attacked</p> <p>6 for plagiarism? Is that what's</p> <p>7 happening here? I mean, what are we</p> <p>8 doing?</p> <p>9 MS. ISIDRO: I'd like to</p> <p>10 continue my questioning.</p> <p>11 BY MS. ISIDRO:</p> <p>12 Q. Dr. Panagos, your Appendix A is</p> <p>13 a list of materials reviewed; correct?</p> <p>14 A. A list of materials reviewed in</p> <p>15 addition to my experience, education,</p> <p>16 background.</p> <p>17 Q. Right. It does not indicate a</p> <p>18 direct citation of a source or a direct</p> <p>19 quotation of a source.</p> <p>20 A. Sorry, what does not indicate a</p> <p>21 direct citation of the source? The</p> <p>22 appendix?</p> <p>23 Q. Correct.</p> <p>24 A. The appendix consists of the</p> <p>25 sources I reviewed. They're listed here.</p>

<p style="text-align: right;">Page 130</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 And in addition to these sources  3 is the education, my experience, my  4 background, my profession as a clinical  5 pharmacist in the managed care space.  6 All of that is what went into  7 producing this report and the opinions  8 here, which are clear.  9 Q. But inclusion of a source on  10 your Appendix A is not an indication that  11 you have directly quoted from that source;  12 correct?  13 MR. HANSEL: Object to the form.  14 There's no such requirement.  15 Why are we doing this? It's a waste  16 of time.  17 A. Could you restate the question  18 or would you mind please repeating that.  19 (Requested portion of record  20 read.)  21 A. Honestly, I don't understand  22 your question. I've already pointed out  23 that the information here in this 74 --  24 sorry.  25 Q. 73.</p>	<p style="text-align: right;">Page 132</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 to even have a source per se because I know  3 that to be true.  4 Q. Okay. Paragraph 74 of your  5 report says: "In many organizations, the  6 P&amp;T committee only performs clinical  7 analysis."  8 Do you see that?  9 A. I wrote that so I see it, yes.  10 Q. And do you see in the first  11 paragraph on page 3 of Exhibit 10 where it  12 says: "In many organizations, the P&amp;T  13 committee only performs clinical analysis"?  14 A. Yeah, yes.  15 Q. Do you see paragraph 74 of your  16 report goes on to say: "If two or more  17 medications are determined to be clinically  18 equivalent, then business elements will  19 determine formulary inclusion or  20 exclusion"?  21 A. Yes.  22 Q. And do you see on page 3 of  23 Exhibit 10 where it says: "If two or more  24 medications are determined to be clinically  25 equivalent, then business elements will</p>
<p style="text-align: right;">Page 131</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 A. 73 that you pointed out is in a  3 reference that I included in my appendix  4 and it's part of the opinion.  5 It's consistent and concise and  6 relevant to the opinion I was asked to  7 render here with regards to safety and  8 effectiveness and generic drugs. All of  9 that is referenced there.  10 So I'm, you know, hoping I'm  11 answering your question because I think  12 you're asking is the material consistent,  13 and it is, it's here, and it's here in my  14 report. So it's found in both places. You  15 can find it, as we have, and it's also here  16 in my report and it's accurate.  17 MR. HANSEL: Let the record  18 reflect that the witness was pointing  19 to Exhibit 10 when saying "it's here."  20 THE WITNESS: Yes, Exhibit 10.  21 Thank you.  22 A. And those statements are  23 accurate, okay? So even based on my  24 experience, those statements -- I can make  25 those statements without necessarily having</p>	<p style="text-align: right;">Page 133</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 determine formulary inclusion or  3 exclusion"?  4 A. Yes.  5 Q. Do you have a footnote or direct  6 citation to Exhibit 10 in paragraph 74 of  7 your report?  8 MR. HANSEL: Object to the form.  9 The document speaks for itself.  10 A. The reference is here in  11 Exhibit 10, which is in my appendix, just  12 part of how I derived the opinions in this  13 report and they are supported by the  14 reference here, Exhibit 10, what we're  15 reviewing together, so...  16 Q. Paragraph 74 does not directly  17 reference Exhibit 10 in any way, does it?  18 MR. HANSEL: Object to the form.  19 A. The entire report is -- and all  20 the references in Appendix A support  21 everything in my report, you know, every  22 single component, in addition to my  23 education and background and experience in  24 the field for 20-plus years. Everything is  25 supported there.</p>

<p style="text-align: right;">Page 134</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 So, again, while there isn't --</p> <p>3 I think you're looking for the little</p> <p>4 footnote, and that isn't there, the</p> <p>5 material is clearly referenced in the</p> <p>6 appendix.</p> <p>7 Q. Do you see in paragraph 75 of</p> <p>8 your report where it says:</p> <p>9 "The overall goal is to develop</p> <p>10 a list of the safest, most effective</p> <p>11 medications that will produce the desired</p> <p>12 goals of therapy at the most reasonable</p> <p>13 cost to the health care system"?</p> <p>14 A. I see it, yes.</p> <p>15 Q. And do you see in the last</p> <p>16 sentence of the first paragraph on page 3</p> <p>17 of Exhibit 10 where it says: "The overall</p> <p>18 goal is to develop a list of the safest,</p> <p>19 most effective medications that will</p> <p>20 produce the desired goals of therapy at the</p> <p>21 most reasonable costs to the health care</p> <p>22 system"?</p> <p>23 A. Yes.</p> <p>24 Q. Can we look at paragraph 78 of</p> <p>25 your report, please.</p>	<p style="text-align: right;">Page 136</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 Q. So essentially, in the case of</p> <p>3 generic drugs, the P&amp;T committee relies on</p> <p>4 the FDA's assessment with respect to the</p> <p>5 generic drug?</p> <p>6 MR. HANSEL: Object to the form.</p> <p>7 A. The P&amp;T committee will reference</p> <p>8 the authoritative source, which is the</p> <p>9 Orange Book, to determine -- to see if the</p> <p>10 generic drug is included.</p> <p>11 That indicates to them that it</p> <p>12 has met the process of approval by the FDA,</p> <p>13 which starts with the ANDA, and that</p> <p>14 process includes the safety and</p> <p>15 effectiveness of that drug, same as the</p> <p>16 original drug product, and that's what it</p> <p>17 considers regarding generic medications.</p> <p>18 Q. And you testified earlier that</p> <p>19 the therapeutic equivalence ratings</p> <p>20 contained in the Orange Book are made by</p> <p>21 the FDA or are determined by the FDA?</p> <p>22 A. The therapeutic equivalence of a</p> <p>23 drug and its substitutability for the</p> <p>24 original or Reference Listed Drug or brand</p> <p>25 drug, original drug product, is made by the</p>
<p style="text-align: right;">Page 135</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 You state in paragraph 78 that:</p> <p>3 "Use of generic drugs that have</p> <p>4 been deemed bioequivalent by the FDA does</p> <p>5 not require a full new round of review or</p> <p>6 approval by a P&amp;T committee."</p> <p>7 What do you mean by "a full new</p> <p>8 round of review or approval by a P&amp;T</p> <p>9 committee"?</p> <p>10 A. That really pertains more to</p> <p>11 brand drugs that are reviewed by a P&amp;T</p> <p>12 committee where they go by a -- they would</p> <p>13 need a more robust or -- you know, process</p> <p>14 of approval by the P&amp;T committee.</p> <p>15 But a generic drug that is</p> <p>16 deemed, you know, therapeutically</p> <p>17 equivalent, therapeutic equivalence by the</p> <p>18 FDA suffices.</p> <p>19 There isn't anything further</p> <p>20 that the P&amp;T committee needs to do in that</p> <p>21 case with regards to a generic drug,</p> <p>22 suffice it meets the criteria, approved</p> <p>23 safe/effective, the P&amp;T committee can then</p> <p>24 consider it to include on their</p> <p>25 formulary -- formularies, plural.</p>	<p style="text-align: right;">Page 137</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 FDA.</p> <p>3 Q. In paragraph 79 of your report</p> <p>4 you say that: "P&amp;T committees will only</p> <p>5 consider adding a generic drug to their</p> <p>6 formulary if it is listed in the Orange</p> <p>7 Book and the Orange Book indicates the</p> <p>8 generic drug is the same as the RLD";</p> <p>9 correct?</p> <p>10 A. Correct.</p> <p>11 Q. So you're saying that inclusion</p> <p>12 in the Orange Book is a requirement, but</p> <p>13 not an automatic trigger for inclusion on</p> <p>14 the formulary; correct?</p> <p>15 A. A generic drug needs to be</p> <p>16 listed in the Orange Book as</p> <p>17 therapeutically quantitative, safe and</p> <p>18 effective, the same as the original drug</p> <p>19 product to be considered for inclusion,</p> <p>20 correct.</p> <p>21 MS. ISIDRO: Let's take a quick</p> <p>22 five-minute break.</p> <p>23 THE VIDEOGRAPHER: This will end</p> <p>24 Media Unit 3.</p> <p>25 Going off the record at 2:46.</p>

<p style="text-align: right;">Page 138</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 (A recess was taken.)  3 THE VIDEOGRAPHER: We're back on  4 the record at 3:05.  5 This will begin Media Unit 4.  6 BY MS. ISIDRO:  7 Q. Dr. Panagos, turning back to  8 your latest report in this litigation,  9 Exhibit 6, if you could take a look at  10 paragraph 80 for me, please.  11 A. Yes.  12 Q. Paragraph 80 states that:  13 "A drug's 'AB' listing in the  14 Orange Book, based as it is on the generic  15 drug manufacturer's ANDA, represents a  16 manufacturer's assurance to TPPs and P&amp;T  17 committees that the generic drug is  18 equivalent to the brand of drug for  19 placement on a prescription drug  20 formulary"; correct?  21 A. Correct.  22 Q. What do you mean by  23 "manufacturer's assurance"?  24 A. Essentially, a manufacturer's  25 promise that their drug product is safe and</p>	<p style="text-align: right;">Page 140</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 similar sentence in your prior report  3 in this litigation, except that  4 instead of saying 'manufacturer's  5 assurance' it said 'manufacturer's  6 warranty'; correct?  7 "Answer: Correct, yes.  8 "Question: Why did you make  9 that change from 'warranty' to  10 'assurance'?"  11 (Testimony resumes.)  12 A. I made the change quite simply  13 to make it in simpler language, and I'm not  14 a lawyer, I'm a clinical pharmacist, and  15 what I'm relaying is that the manufacturers  16 made promises, assurances ensuring that  17 their drug is equivalent to the brand drug.  18 And in doing so, they obtained  19 the FDA approval by the process of the ANDA  20 through the information that they --  21 manufacturers are responsible for providing  22 through that process.  23 And so assurance or warranty,  24 they really mean the same thing. It's the  25 promise that the manufacturers make,</p>
<p style="text-align: right;">Page 139</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 effective, meets all the requirements, has  3 met all the criteria for approval and it is  4 equivalent to the brand drug.  5 Q. Now, you had a very similar  6 sentence in your prior report in this  7 litigation, except that instead of saying  8 "manufacturer's assurance" it said  9 "manufacturer's warranty"; correct?  10 A. Correct, yes.  11 Q. Why did you make that change  12 from "warranty" to "assurance"?  13 ATTENDEE: Excuse me, the room  14 doesn't know the Zoom is still muted,  15 correct?  16 MS. ISIDRO: Let's just have  17 this last question read back and  18 answered and then we can go off the  19 record and deal with the transcript  20 Zoom issue.  21 MR. HANSEL: I object to that.  22 It calls for a legal conclusion.  23 Go ahead.  24 (The following was read back:  25 "Question: Now, you had a very</p>	<p style="text-align: right;">Page 141</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 validation that their product is identical  3 to the brand product, does not deviate in  4 any way in safety and effectiveness, and --  5 and that's why I -- whether it's warranty  6 or assurance, it really denotes the same --  7 the same thing.  8 Q. Dr. Panagos, this paragraph 80  9 has a footnote that mentions a specific  10 reference.  11 Does that language,  12 "manufacturer's assurance," does that come  13 from the reference or is that your own  14 language?  15 MR. HANSEL: Object to the form.  16 A. I don't recall whether it's from  17 the reference or my own language, but I  18 know that to be accurate and true, that  19 when the manufacturer provides their  20 information by the process of the ANDA,  21 that is part of the process.  22 The -- very clear about that,  23 that they need to demonstrate sameness to  24 the Reference Listed Drug product.  25 And so that's accurate and true.</p>

<p style="text-align: right;">Page 142</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 And whether it says assurance or some other  3 word, that is -- doesn't negate the fact  4 that that's the process and what the  5 expectation is.  6 MS. ISIDRO: Let's go ahead and  7 mark the next exhibit.  8 (Exhibit 11 marked for  9 identification, multi-page document  10 titled "ASHP Guidelines on the  11 Pharmacy and Therapeutics Committee  12 and the Formulary System.")  13 BY MS. ISIDRO:  14 Q. Doctor, you have in front of you  15 now what's been marked as Exhibit 11;  16 correct?  17 A. Yes.  18 Q. And is that the reference that's  19 listed in footnote 9 of your report?  20 A. Yes.  21 Q. And could you look through this,  22 please, and just refresh your recollection  23 as to whether that manufacturer's assurance  24 language comes from this reference.  25 MR. HANSEL: Object to the form.</p>	<p style="text-align: right;">Page 144</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 And so the while the word  3 "assurance" is not explicitly stated, drugs  4 appropriate for therapeutic interchange,  5 the word "appropriate" denotes that that  6 drug has been deemed and went through the  7 criteria of -- by the FDA which requires  8 the ANDA, which requires the manufacturer  9 to submit the appropriate information  10 consistent with the ANDA to assure that  11 their drug is meeting the criteria for  12 approval, so I hope that answers your  13 question.  14 Q. And, Dr. Panagos, there is no  15 reference to the manufacturer in that  16 section of page 912 that you referenced;  17 correct?  18 A. In that section, no.  19 But when we're talking about  20 drugs for therapeutic interchange and drugs  21 appropriate, we're talking about drugs that  22 have met the criteria for approval through  23 the ANDA that the manufacturer submits, the  24 information for review and approval.  25 Q. Now, Doctor, you've already</p>
<p style="text-align: right;">Page 143</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 This is a lengthy 12-page  3 document.  4 Please take your time and review  5 it as much as you need to.  6 A. On page 912, in the "Therapeutic  7 Interchange" section in Column 2, "Drugs  8 appropriate for therapeutic" -- sorry, let  9 me go a little bit further.  10 There is a reference there to  11 "therapeutic effects and safety profiles,"  12 and so they're expected to have a similar  13 therapeutic effect and safety profile when  14 administered to patients in therapeutically  15 equivalent doses.  16 There's reference to  17 "therapeutic interchange."  18 "Drugs appropriate for  19 therapeutic interchange are drug products  20 with different chemical structures that are  21 expected to have similar therapeutic  22 effects and safety profiles when  23 administered to patients in therapeutically  24 equivalent doses," and that's consistent  25 with what we've been discussing here.</p>	<p style="text-align: right;">Page 145</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 testified that the FDA is the one who  3 determines whether a particular drug will  4 receive an AB rating; correct?  5 A. What I said was that the FDA  6 approves, but they approve via the ANDA  7 that is submitted.  8 An ANDA is submitted by the  9 manufacturer, and the manufacturer is  10 responsible for the information they're  11 providing within the ANDA that the FDA will  12 use to determine if a drug is meeting the  13 criteria for approval or not.  14 So while the FDA -- so I just  15 want to be clear what you're stating. The  16 FDA approves, but through the process of  17 the ANDA that begins with the manufacturer,  18 and it's the manufacturer's responsibility  19 to provide the information within the ANDA  20 that the FDA approves based on that  21 information that the manufacturer provides,  22 to be clear.  23 Q. Now, approval and AB rating are  24 two different things; right?  25 A. If we're talking about a generic</p>



<p style="text-align: right;">Page 146</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph. 2 and they're looking at the ANDA and -- for 3 therapeutic interchange -- can you restate 4 or be more clear on what you're asking, 5 please? 6 Q. The fact that an ANDA is 7 approved does not necessarily mean that the 8 drug that is subject to that ANDA will 9 receive an AB rating; correct? 10 MR. HANSEL: Object to the form. 11 A. The process of evaluation of the 12 ANDA is contingent upon the information 13 that the manufacturers provide and must 14 suffice the criteria that the FDA requires 15 for approval and/or an AB rating, 16 therapeutic interchange. 17 And so to be -- it all ties back 18 to the ANDA and the information that the 19 manufacturer provides for evaluation by the 20 FDA. 21 MR. HANSEL: We'd like to take a 22 short break. 23 Five minutes. 24 MS. ISIDRO: Sure. 25 THE VIDEOGRAPHER: Going off the</p>	<p style="text-align: right;">Page 148</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph. 2 assurance, that the drug is safe and 3 effective on an ongoing basis, and that is 4 the obligation of the manufacturer. 5 Q. So the ongoing obligations that 6 you're referring to are the ongoing 7 obligations with respect to the ANDA under 8 the FDA regulatory scheme? 9 MR. HANSEL: Object to the form. 10 A. The obligation of the 11 manufacturer begins with the ANDA, 12 submitting the right information, obtaining 13 -- meeting the criteria set forth by the 14 FDA for approval. 15 And then if you look at Section 16 1.2 of the Orange Book in subset 5, it 17 further talks about the manufacturer, or 18 "they" are all -- they are -- the 19 manufacturers of the drug -- in compliance 20 with Good Manufacturing Practice 21 regulations as set forth by the FDA. 22 So the manufacturer has to 23 continue to -- it's their obligation to 24 continue to demonstrate that their drug is 25 in compliance with Good Manufacturing</p>
<p style="text-align: right;">Page 147</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph. 2 record at 3:19. 3 (A recess was taken.) 4 THE VIDEOGRAPHER: We're back on 5 the record at 3:32. 6 BY MS. ISIDRO: 7 Q. Dr. Panagos, if I understood 8 your testimony before the break correctly, 9 what you were clarifying is that when you 10 refer to the manufacturer's assurance in 11 your report, what you're referring to is 12 the accuracy of the information that the 13 manufacturer submitted to the FDA? 14 MR. HANSEL: Object to the form. 15 A. The accuracy of the information 16 that they submitted to the FDA, yes. 17 But also their ongoing 18 obligation to be consistent or assuring 19 that their drug continues to be safe and 20 effective, and that includes the 21 information that they submitted in the 22 ANDA, including the manufacturing of that 23 drug being consistent with, I think we 24 spoke earlier, the Good Manufacturing 25 Practices that continue to provide that</p>	<p style="text-align: right;">Page 149</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph. 2 Practices, that it's safe, that it's 3 effective, that it does not consist of a 4 human carcinogen and that it's safe for 5 use. 6 Q. Doctor, in your response there, 7 you referenced Section 1.2 of the Orange 8 Book in subset 5. I just want to make sure 9 I'm looking at the correct thing that 10 you're referencing. 11 This is Exhibit 9, the Orange 12 Book preface. And you're looking at number 13 5, which starts at the very end of page 4 14 of this document and continues on page 5 of 15 this document? 16 A. Yes, correct. 17 Q. And that is in a paragraph 18 that's talking about the FDA's criteria for 19 determining therapeutic equivalence; 20 correct? 21 A. Correct, yes. 22 Q. So, again, when you're referring 23 to ongoing obligations applicable to the 24 manufacturer, you're referring to ongoing 25 obligations under the FDA regulatory scheme</p>

<p style="text-align: right;">Page 150</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 that's applicable to drugs approved  3 pursuant to the ANDA process?  4 A. Ongoing obligations of the  5 manufacturer.  6 Q. Post approval?  7 MR. HANSEL: Object to the form.  8 A. Manufacturer is obligated  9 throughout the entire process, right, they  10 submit the ANDA, all that material, that's  11 their obligation. Approval, the  12 manufacturing of that drug that is  13 consistent with Good Manufacturing  14 Practices, that's their obligation.  15 The entire process is their  16 obligation in compliance with the FDA  17 regulations and to continue to adhere to  18 that.  19 Having a human carcinogen in  20 their medication is not consistent with  21 Good Manufacturing Practices. It's not  22 safe nor an effective medication for use.  23 Q. Doctor, again, regardless of  24 whether we're talking about preapproval or  25 post-approval obligations, the obligations</p>	<p style="text-align: right;">Page 152</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 United States.  3 Q. Doctor, we'll get to the later  4 sections of your report, including any  5 purported breach of obligations or anything  6 to that effect that's described in your  7 report.  8 But for right now we're talking  9 about what you mean by "manufacturer's  10 assurance"; right? And one of the things  11 that you mentioned with respect to  12 manufacturer's assurance is the accuracy of  13 the representations that they made in their  14 ANDA submissions; correct?  15 MR. HANSEL: Object to the form.  16 You may answer.  17 A. Part of the assurance consists  18 of the accuracy of their information during  19 the ANDA process. It does not end there.  20 It is their obligation to  21 continue that assurance throughout the  22 manufacturing process.  23 Let me be clear on that.  24 Q. And my question was one of the  25 things that you mentioned was the accuracy</p>
<p style="text-align: right;">Page 151</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 that you are referring to are the  3 obligations applicable under the FDA's  4 regulatory scheme; correct?  5 MR. MESTRE: Object to the form.  6 A. We're talking about generic  7 drugs and the process that they must go by  8 to be -- the process they must go through  9 according to the FDA to receive approval to  10 be considered therapeutically  11 substitutable, to be considered for  12 placement in the Orange Book, which renders  13 them therapeutically equivalent, same as  14 the Reference Listed Drug, identical, safe  15 and effective, adhering to Good  16 Manufacturing Practices, which is critical.  17 Again, the drug -- the drugs  18 we're talking about consisted of a  19 carcinogen, and that is not consistent with  20 Good Manufacturing Practices and it  21 deviates from the sameness that we're  22 referring to in the -- that they must  23 adhere to, that they're obligated to adhere  24 to in the process that is required to have  25 a generic drug considered for use in the</p>	<p style="text-align: right;">Page 153</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 of the ANDA submission, the accuracy of the  3 information in the ANDA submission.  4 A. I answered that that is part of  5 the process, but the obligation does not  6 end there. It is --  7 Q. And so another part that you're  8 referring to --  9 MR. HANSEL: Excuse me, excuse  10 me, please allow the witness to  11 answer. You've been holding out your  12 hand to ask her to stop answering, and  13 she's allowed to complete her answer  14 and then you can ask the next  15 question.  16 Object to the form.  17 A. Let's be clear on the process.  18 It's -- for generic drugs to  19 really be considered for use in the -- in  20 the United States, the process begins with  21 a generic manufacturer submitting an ANDA  22 application of all the requirements that  23 they're obligated to adhere to, to go  24 through that process for the FDA to  25 consider the sameness.</p>

<p style="text-align: right;">Page 154</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 And -- and that obligation by  3 the manufacturer continues in the  4 manufacturing of that drug, consistent with  5 Good Manufacturing Practices that continue  6 to demonstrate or assure the public, who  7 will be using this drug, that it's free of  8 a carcinogen, it's safe and effective.  9 This is what we're talking  10 about, is what we're boiling it down to,  11 and that process is clearly outlined.  12 I have referred to Section 1.2,  13 subset 5, where that obligation continues  14 and the Good Manufacturing Practice  15 obligations, as outlined in this section --  16 as noted in this section. And so I believe  17 that would answer your question.  18 MR. HANSEL: Let the record  19 reflect the witness is referring to  20 Exhibit 9.  21 THE WITNESS: Exhibit 9.  22 BY MS. ISIDRO:  23 Q. Okay.  24 MS. ISIDRO: Would you just read  25 back the last question that's on the</p>	<p style="text-align: right;">Page 156</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 Q. Is there anything other than the  3 FDA-imposed requirements applicable to that  4 drug that you are referring to when you  5 refer to those ongoing obligations?  6 A. Could you restate the question,  7 please?  8 Q. Is there anything other than  9 FDA-imposed requirements applicable to that  10 particular drug that you are referring to  11 when you are referring to ongoing  12 obligations of the manufacturer?  13 A. All the regulations set forth by  14 the FDA, including Good Manufacturing  15 Practices and other regulations that are  16 within -- that they set forth in order for  17 that drug to gain approval and gain entry  18 into the Orange Book and deem it  19 therapeutically equivalent, safe and  20 effective, free of contaminants and  21 certainly carcinogens.  22 Q. Anything other than all  23 applicable FDA regulations that you are  24 referring to when you refer to the ongoing  25 requirements applicable to the</p>
<p style="text-align: right;">Page 155</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 record, please.  3 (Requested portion of record  4 read.)  5 BY MS. ISIDRO:  6 Q. So, Dr. Panagos, when you  7 referenced the manufacturer's assurance in  8 your report, one of the things that you are  9 referring to is the accuracy of the  10 information contained in their ANDA  11 submission, and another thing that you are  12 referring to is their ongoing obligations,  13 correct, post approval.  14 Are those --  15 A. The assurance refers to the  16 entire process with regards to that  17 particular drug, the entire process.  18 Q. And that process is established  19 by the FDA and the FDA's regulations  20 applicable to that drug; correct?  21 A. The manufacturer must adhere  22 with the process, what the criteria of the  23 FDA is, throughout the entire process. The  24 manufacturer must adhere to those, must  25 continue to adhere to those.</p>	<p style="text-align: right;">Page 157</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 manufacturers?  3 MR. HANSEL: Object to the form.  4 A. Not sure I'm following your  5 question but I'm going to answer in the way  6 that I know to be accurate in that a  7 generic manufacturer seeking approval of  8 their drug must submit an ANDA to the FDA  9 that needs to adhere to the criteria the  10 FDA sets forth that includes safety and  11 effectiveness.  12 It also includes adherence and  13 ongoing obligation to Good Manufacturing  14 Practices to manufacture that drug -- for  15 manufacturing of that drug to allow that to  16 be considered for use by the public in the  17 United States, considered for inclusion on  18 formularies, safe and effective and free of  19 human carcinogens.  20 Q. Are Good Manufacturing Practices  21 established by the FDA?  22 MR. HANSEL: Object to the form.  23 Foundation.  24 A. That was out -- that was outside  25 the scope of this opinion. But I know as a</p>

<p style="text-align: right;">Page 158</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 pharmacist that Good Manufacturing  3 Practices must be adhered to, and if  4 they're not, that product has been  5 adulterated in some way, does not comply  6 with Good Manufacturing Practices, unsafe  7 and really just unsafe for use, so...  8 In our professional practice, my  9 professional practice, that says it all.  10 Unsafe for use does not comply with Good  11 Manufacturing Practices and not safe for --  12 for the public to take.  13 Q. Doctor, again, I'm trying to  14 understand the bases for your opinions that  15 are expressed in this report.  16 And one of the opinions relates  17 to manufacturer's assurance, as you've  18 referred to it.  19 And you've explained that what  20 you are referring to as the manufacturer's  21 assurance deals with the accuracy of the  22 information submitted to FDA in the  23 approval process, as well as the  24 manufacturer's compliance with what you've  25 referred to as ongoing obligations that</p>	<p style="text-align: right;">Page 160</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 Q. You're referring to an  3 obligation. I just want to understand  4 where that obligation comes from.  5 A. The obligation originates with  6 the manufacturer.  7 It's the manufacturer who is  8 seeking -- who sets out -- puts forth their  9 ANDA. They're seeking approval of their  10 drug.  11 Approval of the drug is not  12 enough, right? They have to manufacture  13 the drug and ensure then that their drug is  14 being manufactured consistent with all the  15 requirements, including Good Manufacturing  16 Practices, that assure or validate,  17 promise, make absolutely certain beyond any  18 doubt that their product is safe and  19 effective, identical to the original  20 product without a carcinogen.  21 And so that is how I see the  22 process. That's what I've asked to be  23 rendered -- render an opinion on, and  24 that's what I know to be true, so...  25 Q. Those are regulatory obligations</p>
<p style="text-align: right;">Page 159</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 continue after the time of approval;  3 correct?  4 MR. HANSEL: Object to the form.  5 BY MS. ISIDRO:  6 Q. Including current Good  7 Manufacturing Practices.  8 MR. HANSEL: Object to the form.  9 BY MS. ISIDRO:  10 Q. Is that correct?  11 A. I'm going to summarize and say  12 that it all resides with the manufacturer.  13 It's their obligation to ensure  14 their drug meets the criteria, ensure that  15 it's safe, ensure that it doesn't have a  16 carcinogen in it and that it continues to  17 meet that obligation, you know, on an  18 ongoing basis so that it can continue to be  19 considered for use.  20 Q. Who or what imposes that  21 obligation?  22 MR. HANSEL: Object to the form.  23 Foundation. Calls for a legal  24 conclusion.  25 BY MS. ISIDRO:</p>	<p style="text-align: right;">Page 161</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 imposed by the FDA; correct?  3 MR. HANSEL: Object to the form.  4 Calls for a legal conclusion.  5 A. The process is set forth by the  6 FDA, but the manufacturer's obligation is  7 to adhere to the process and criteria and  8 all of the requirements that the FDA needs  9 to assure that drug is safe, in compliance  10 with Good Manufacturing Practices and safe  11 for the public or humans to use.  12 Q. Doctor, would you agree that  13 inclusion of products in the Orange Book is  14 independent of any current regulatory  15 action being taken administratively or  16 judicially against a drug product?  17 A. Could you repeat the question.  18 (Requested portion of record  19 read.)  20 A. Inclusion in the Orange Book  21 indicates that the product is  22 therapeutically equivalent to the Reference  23 Listed Drug. Any deviation from that is  24 the obligation of the manufacturer to  25 report, set forth.</p>

<p style="text-align: right;">Page 162</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 So if there was a deviation from</p> <p>3 therapeutic equivalence, the drug would</p> <p>4 absolutely not be in the Orange Book.</p> <p>5 Q. Doctor, could you take a look at</p> <p>6 Exhibit 9, the first page of Exhibit 9,</p> <p>7 fourth line down in the first paragraph.</p> <p>8 Can you read that sentence that</p> <p>9 begins with the word "inclusion."</p> <p>10 A. "The main criterion for the</p> <p>11 inclusion of any" --</p> <p>12 Q. The next line down. The</p> <p>13 sentence that begins with "inclusion" at</p> <p>14 the end of the next line.</p> <p>15 A. Oh, sorry, pardon me.</p> <p>16 Q. No, no problem.</p> <p>17 A. "Inclusion of products in the</p> <p>18 Orange Book is independent of any current</p> <p>19 regulatory action being taken</p> <p>20 administratively or judicially against a</p> <p>21 drug product."</p> <p>22 Q. Okay. So that's expressly</p> <p>23 stated in the preface to the Orange Book;</p> <p>24 correct?</p> <p>25 A. I just read it.</p>	<p style="text-align: right;">Page 164</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 therapeutic interchange.</p> <p>3 Q. Doctor, if you could look at</p> <p>4 paragraph 96 of your report.</p> <p>5 You state that: "Manufacturers</p> <p>6 are responsible for understanding their</p> <p>7 processes, which includes preventing the</p> <p>8 presence of unacceptable contaminants or</p> <p>9 impurities, meaning any substance that does</p> <p>10 not belong in the medication."</p> <p>11 When you say "meaning any</p> <p>12 substance that does not belong in the</p> <p>13 medication," does that refer to</p> <p>14 contaminants as well as impurities or is</p> <p>15 that referring just to impurities?</p> <p>16 MR. HANSEL: Object to the form.</p> <p>17 A. Meaning -- meaning any</p> <p>18 substance, contaminant, impurity, anything</p> <p>19 that does not -- that is not safe or -- or</p> <p>20 does not belong in -- in this case, we're</p> <p>21 talking the generics, right, so any</p> <p>22 substance that is not consistent with the</p> <p>23 Reference Listed Drug, with the brand drug,</p> <p>24 anything that deviates from that --</p> <p>25 contaminant, impurity, call it what you</p>
<p style="text-align: right;">Page 163</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 Q. And, Doctor, are you aware of</p> <p>3 whether the VCDs at issue in this</p> <p>4 litigation were listed --</p> <p>5 (Noise interruption.)</p> <p>6 BY MS. ISIDRO:</p> <p>7 Q. Doctor, are you aware of whether</p> <p>8 the VCDs at issue in this litigation were</p> <p>9 listed in the Orange Book at all times</p> <p>10 during which they were on the market?</p> <p>11 A. I know they were listed in the</p> <p>12 Orange Book when they met the criteria as</p> <p>13 set forth by the FDA and --</p> <p>14 THE WITNESS: Can you restate</p> <p>15 the question on the latter half of it,</p> <p>16 please, so I can be clear what she's</p> <p>17 asking. Thank you.</p> <p>18 (Requested portion of record</p> <p>19 read.)</p> <p>20 A. Not sure their listing time</p> <p>21 frame, but what I am referring to is the</p> <p>22 process by which the drugs are -- meet the</p> <p>23 criteria for inclusion in the Orange Book</p> <p>24 and what that means, and what that means in</p> <p>25 terms of safety and effectiveness and</p>	<p style="text-align: right;">Page 165</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 will -- any substance that does not belong</p> <p>3 in the medication, certainly if it is</p> <p>4 carcinogenic absolutely does not belong.</p> <p>5 Q. And, Doctor, I just want to</p> <p>6 understand, in paragraph 96, are you using</p> <p>7 the terms "contaminants" and "impurities"</p> <p>8 interchangeably?</p> <p>9 MR. HANSEL: Object to the form.</p> <p>10 A. I have it there as "contaminants</p> <p>11 or impurities." Either way, it's a</p> <p>12 substance that does not belong in the</p> <p>13 medication one way or another, however you</p> <p>14 read it. I have it there listed as</p> <p>15 "contaminants or impurities," neither of</p> <p>16 which belong in a medication, certainly</p> <p>17 what we're discussing here.</p> <p>18 Q. As you're using the terms in</p> <p>19 paragraph 96, is there a distinction</p> <p>20 between "contaminants" and "impurities"?</p> <p>21 MR. HANSEL: Object to the form.</p> <p>22 A. They both refer to a substance</p> <p>23 that does not belong in the medication or</p> <p>24 in a medication and is unsafe, both denote</p> <p>25 that and refer to that.</p>

<p style="text-align: right;">Page 166</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 So, again, whether we're talking</p> <p>3 a contaminant or impurity -- and in this</p> <p>4 case, a human carcinogen -- does not belong</p> <p>5 in a medication.</p> <p>6 Q. Do you consider NDMA to be a</p> <p>7 contaminant?</p> <p>8 A. It did not belong in the</p> <p>9 medication, and, yes, it could be</p> <p>10 considered a contaminant, yes.</p> <p>11 Q. Do you consider NDMA -- excuse</p> <p>12 me -- do you consider NDEA to be a</p> <p>13 contaminant?</p> <p>14 A. Same response, and that is, you</p> <p>15 know, it's been established that those</p> <p>16 products are human carcinogens and did not</p> <p>17 belong in the generic product, inconsistent</p> <p>18 -- their presence in the product rendered</p> <p>19 them not equivalent, not the same as the</p> <p>20 Reference Listed Drug, to be clear.</p> <p>21 We talked earlier how both of</p> <p>22 those components have been classified as</p> <p>23 probable human carcinogens and so either of</p> <p>24 those should not have been in the generic</p> <p>25 medications.</p>	<p style="text-align: right;">Page 168</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 my report.</p> <p>3 Q. So the answer is no, you don't</p> <p>4 know one way or the other?</p> <p>5 A. No.</p> <p>6 Q. And do you know one way or the</p> <p>7 other whether NDEA was ever found in the</p> <p>8 Reference Listed Drug?</p> <p>9 A. Same answer.</p> <p>10 Q. Do you know one way or the other</p> <p>11 whether the RLD was ever tested for NDMA at</p> <p>12 any point prior to 2018?</p> <p>13 A. That was outside the scope of my</p> <p>14 report. My report is focused on the</p> <p>15 generic product which was found to have the</p> <p>16 contaminants, human carcinogens, and not</p> <p>17 equivalent to the brand product, reference</p> <p>18 listed product.</p> <p>19 Q. So the answer to my question is</p> <p>20 no, you do not know one way or the other?</p> <p>21 A. The answer to your question is</p> <p>22 it was outside the scope of my report and</p> <p>23 that the focus of the report is on the</p> <p>24 generic having the contaminants and not</p> <p>25 being equivalent or same, effective -- safe</p>
<p style="text-align: right;">Page 167</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 Q. Do you consider NDMA to be an</p> <p>3 impurity?</p> <p>4 A. Again, those products are known</p> <p>5 carcinogens. I am not a toxicologist. I'm</p> <p>6 not going to speculate on the details of</p> <p>7 either of those. But I do know that both</p> <p>8 of those were present, found, contaminant</p> <p>9 in the generics that -- and that they are</p> <p>10 carcinogens, and so the generic was no</p> <p>11 longer equivalent to the brand and that's</p> <p>12 what's important here.</p> <p>13 Q. Do you know whether NDMA was</p> <p>14 ever found in the RLD?</p> <p>15 A. That was not within the scope of</p> <p>16 my opinion or my report.</p> <p>17 Q. So you don't know one way or the</p> <p>18 other because it wasn't in the scope?</p> <p>19 A. I do know that the reference</p> <p>20 listed product was approved by the FDA and</p> <p>21 went through the NDA process for approval.</p> <p>22 Q. But you don't know one way or</p> <p>23 the other whether NDMA was ever found in</p> <p>24 the Reference Listed Drug?</p> <p>25 A. That was not within the scope of</p>	<p style="text-align: right;">Page 169</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 and effective to the Reference Listed Drug,</p> <p>3 brand drug.</p> <p>4 Q. So, again, my question is a</p> <p>5 yes-or-no question.</p> <p>6 Do you know one way or the other</p> <p>7 whether the RLD was ever tested for NDMA at</p> <p>8 any point prior to 2018?</p> <p>9 MR. HANSEL: Object to the form.</p> <p>10 A. It was outside the scope of my</p> <p>11 report, no.</p> <p>12 Q. Do you know one way or the other</p> <p>13 whether the Reference Listed Drug was ever</p> <p>14 tested for NDEA prior to 2018?</p> <p>15 A. Same answer.</p> <p>16 MS. ISIDRO: We'll go off the</p> <p>17 record for a moment.</p> <p>18 THE VIDEOGRAPHER: This will end</p> <p>19 Media Unit 4.</p> <p>20 Going off the record at 4:08.</p> <p>21 (A recess was taken.)</p> <p>22 THE VIDEOGRAPHER: We're back on</p> <p>23 the record at 4:09.</p> <p>24 This will begin Media Unit 5.</p> <p>25 BY MS. ISIDRO:</p>



<p style="text-align: right;">Page 170</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph. 2 Q. Doctor, looking at Section Roman 3 Numeral XI of your report entitled "The 4 Medication Guide," it starts on page 20, do 5 you know whether a Medication Guide was 6 applicable to any of the VCDs at issue in 7 this litigation? 8 A. Medication Guides are provided 9 to patients so they can understand their 10 medication, so it would be applicable to 11 all medications. 12 Q. So, Doctor, it is your testimony 13 that the FDA requires Medication Guides for 14 all prescription drug products? 15 A. The FDA requires that patients 16 understand how to use their medication and 17 that there's guides, sources, resources for 18 them to refer to on how to use that -- 19 those medications. 20 Those sources come from the 21 manufacturer, but the FDA approves that 22 whole process we talked about, and so 23 patients should be receiving a guide on how 24 to and what their medication, and they do. 25 They do receive guides and when</p>	<p style="text-align: right;">Page 172</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph. 2 Q. And this is a page from the 3 FDA's website relating to Medication 4 Guides; correct? 5 A. Yes. 6 Q. And under the second question, 7 "Why do some medicines have Medication 8 Guides?", this page states that "FDA 9 requires that Medication Guides be issued 10 with certain prescribed drugs and 11 biological products when the Agency 12 determines that," and then it lists certain 13 criteria; correct? 14 A. It lists three bullet points. 15 Q. Right. So the FDA only requires 16 Medication Guides for certain prescribed 17 drugs and biological products when these 18 three bullet point criteria are met; 19 correct? 20 MR. HANSEL: Object to the form. 21 Foundation. 22 A. What it states there is I 23 believe what you read, where the "FDA 24 requires that Medication Guides be issued 25 with certain prescribed drugs and</p>
<p style="text-align: right;">Page 171</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph. 2 they're provided their medication at the 3 pharmacy level they're receiving a guide 4 that is telling them about their 5 medication, typically what it's used for, 6 any side effects. There's information in 7 there that's pertinent to the use of that 8 medication for a patient. 9 Q. And is that the information 10 that's typically stapled to the outside of 11 the bag when you pick up a prescription at 12 a pharmacy? 13 A. It could be, yes. 14 Q. Is that what you're referring to 15 when you refer to a Medication Guide? 16 A. It could be, yes. 17 MS. ISIDRO: Can we mark the 18 next exhibit, please. 19 (Exhibit 12 marked for 20 identification, two-page document 21 titled "Medication Guides.") 22 BY MS. ISIDRO: 23 Q. Doctor, you have in front of you 24 what's been marked as Exhibit 12; correct? 25 A. Correct.</p>	<p style="text-align: right;">Page 173</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph. 2 biological products when the Agency 3 determines that: 4 Bullet point 1, "certain 5 information is necessary to prevent serious 6 adverse effects; bullet point 2, "patient 7 decision-making should be informed by 8 information about a known serious side 9 effect with a product or; bullet point 3, 10 "patient adherence to directions for the 11 use of a product are essential to its 12 effectiveness," all of which are applicable 13 to the medications we're discussing. 14 Q. Doctor, are you aware that the 15 FDA maintains a database of drugs that 16 require Medication Guides? 17 A. Yes, I am aware. 18 Q. Did you check that database to 19 see whether any VCDs were listed? 20 A. I do know that Medication Guides 21 are distributed to patients for the bullet 22 points we just went over so that patients 23 are informed and they're knowledgeable 24 about their drugs. 25 Part of my obligation as a</p>

44 (Pages 170 - 173)

<p style="text-align: right;">Page 174</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 pharmacist is to help patients be better  3 informed about the medication they're  4 taking and their health journey.  5 A Medication Guide is essential  6 for a patient so that they're aware of what  7 they're taking, they're in the know, they  8 have some cognizance of the medication and  9 what they're taking it for, and certainly  10 if it's something they should be looking to  11 in terms of a side effect or a contaminant  12 or something that would affect that  13 medication, its safety and affect their  14 health.  15 So it's important for patients  16 to know what they're taking and informed  17 about their medications via guide, via  18 counseling through their pharmacist and  19 other resources that patients or their  20 prescribers may look to so that patients  21 are feeling assured that their medication  22 is safe and effective for the reason  23 they're taking it.  24 Q. Doctor, did you check the FDA's  25 Medication Guide database to see whether</p>	<p style="text-align: right;">Page 176</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 contaminated and unsafe, and that all --  3 that obligation and that responsibility  4 lies with the manufacturer.  5 MS. ISIDRO: I'll have this  6 marked as Exhibit 13, please.  7 (Exhibit 13 marked for  8 identification, multi-page document  9 titled "Medication Guides.")  10 BY MS. ISIDRO:  11 Q. Doctor, you have in front of you  12 Exhibit 13. I'm going to represent to you  13 that this is a copy, a printout of the  14 FDA's Medication Guides database.  15 Is Diovan listed as one of the  16 drugs that requires a Medication Guide?  17 A. I don't see it listed here.  18 Q. Is Exforge one of the drugs  19 that's listed as requiring a Medication  20 Guide?  21 A. I don't see it listed here.  22 Q. Do you see any VCDs that are  23 listed as requiring a Medication Guide?  24 MR. HANSEL: I object to the  25 form of the question due to the date</p>
<p style="text-align: right;">Page 175</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 any VCDs were listed as being required to  3 have a Medication Guide by FDA?  4 A. No, I do not recall, you know,  5 precisely if you're asking if they're  6 required. And I think we're -- we're  7 harping on a point that is taking us away  8 from the fact that it's the obligation, you  9 know, of the manufacturer to -- you know,  10 we're going -- they're a safe and effective  11 product, and that they must adhere to the  12 approval process through the ANDA and the  13 Good Manufacturing Practices and that they  14 continue to do so.  15 When that drug -- when they do  16 all those things and that drug is available  17 for prescribing and available for patients  18 to use, that kind of validates that it  19 meets all those criteria and everything  20 that it needs to in order for it to be  21 safe.  22 Whether that's a requirement or  23 not on the products we're talking about,  24 and the question that you ask doesn't take  25 away the fact that the product was still</p>	<p style="text-align: right;">Page 177</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 of this document.  3 A. Is this a recent document? Is  4 this a recent printout? Did you reference  5 this recent?  6 Q. Doctor, if you could just answer  7 my question. You can have it read back if  8 you need to have it read back.  9 MR. HANSEL: Object to the form.  10 THE WITNESS: You could read it  11 back.  12 Thank you.  13 (Requested portion of record  14 read.)  15 A. I do not see any on this  16 Medication Guide that you provided. I'm  17 not sure when it's from or when it was  18 obtained, but in this version that you're  19 showing me, I do not see.  20 Q. Doctor, are you personally aware  21 of FDA ever requiring a Medication Guide to  22 be included with any VCD?  23 A. The -- I've been a pharmacist a  24 long time, and requirement or not, it is  25 always advisable for the patient to be</p>

<p style="text-align: right;">Page 178</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 informed of their medication.  3 We've all been to the pharmacy.  4 We want to know what we're taking and we  5 want to know about our drug, and we  6 certainly want to know if it's safe and  7 effective and we absolutely want to know if  8 there's a carcinogen to it.  9 And when it comes to a generic,  10 we want to trust that that generic is  11 equivalent, same as the brand.  12 Requirement or not, those are  13 the expectations.  14 Q. So, Doctor, are you personally  15 aware one way or the other of FDA ever  16 requiring the Medication Guide be included  17 with any VCD?  18 A. No, but I've answered the  19 question previously as to how I regard that  20 in my professional scope as a pharmacist.  21 Q. Doctor, you acknowledge in your  22 report that there are federal regulations  23 applicable to Medication Guides; correct?  24 A. Yes.  25 MS. ISIDRO: Let's go ahead and</p>	<p style="text-align: right;">Page 180</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 correct?  3 A. Yes.  4 Q. And, Doctor, turning to Section  5 XII of your report, "Summary of Opinions,"  6 is this essentially a summary of the  7 opinions that you've expressed elsewhere in  8 your report?  9 A. Yes.  10 Q. And in paragraph Roman Numeral  11 III, under your summary of opinions, you  12 state that: "Manufacturers have ultimate  13 responsibility for their quality process,  14 manufacturing practices, safety obligations  15 and all of the information presented in the  16 ANDA which is reported to the FDA to obtain  17 approval"; correct?  18 A. Yes, that's correct.  19 Q. Am I understanding correctly  20 that the quality process, manufacturing  21 process, safety obligations that you're  22 referring to there, that that is all part  23 of what is reported to the FDA to obtain  24 approval?  25 MR. HANSEL: Object to the form.</p>
<p style="text-align: right;">Page 179</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 take a short break.  3 THE VIDEOGRAPHER: Going off the  4 record at 4:27.  5 (A recess was taken.)  6 THE VIDEOGRAPHER: We're back on  7 the record at 4:53.  8 BY MS. ISIDRO:  9 Q. Dr. Panagos, looking at Section  10 X of your report, that section is entitled  11 "The Prescription Label"; correct?  12 A. Yes, correct.  13 Q. And it consists of paragraph  14 127, with its subparts; and 128, with a  15 diagram or demonstrative that appears in  16 the bottom half of page 19?  17 A. That is correct.  18 Q. The prescription label that is  19 discussed in this section of your report,  20 is that the label that's on the bottle that  21 is actually dispensed to the patient?  22 A. Yes.  23 Q. And so that label is generated  24 by the pharmacy itself that is dispensing  25 the product, not by the manufacturer;</p>	<p style="text-align: right;">Page 181</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 A. I'm referring to all of the  3 processes involved with regards to that  4 medication, which includes the approval,  5 quality of practices -- processes,  6 practices, manufacturing practices,  7 including Good Manufacturing Practices and  8 ongoing obligations.  9 Q. Okay. So what you're referring  10 to in this paragraph, Roman Numeral III,  11 includes the ongoing post-approval  12 requirements that you referenced earlier?  13 A. Yes.  14 Q. Have you reviewed the quality  15 process for any VCD manufacturer that's  16 involved in this litigation?  17 A. No.  18 Q. Have you reviewed the  19 manufacturing practices for any VCD  20 manufacturer that's involved in this  21 litigation?  22 A. No.  23 Q. Have you reviewed the ANDA  24 information presented to FDA to obtain  25 approval for any of the VCDs involved in</p>

<p style="text-align: right;">Page 182</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 this litigation?  3 A. No.  4 Q. You state in paragraph 10 of  5 your -- Roman Numeral X of your Summary of  6 Opinions that: "TPPs would not have  7 selected these products for inclusion on  8 their drug formularies or paid for these  9 medications if they were aware of the  10 potential presence of contaminants within  11 the products."  12 Are the contaminants that you  13 reference there NDMA and/or NDEA?  14 A. Yes.  15 Q. Are you referring to anything  16 other than NDMA and/or NDEA when you  17 reference "contaminants" in that Roman  18 Numeral X?  19 A. With regard to these  20 medications, the contaminants I'm referring  21 to are the ones you referenced.  22 Q. And what is your basis for  23 opining that the TPPs would not have  24 selected these products for inclusion on  25 their drug formularies or paid for these</p>	<p style="text-align: right;">Page 184</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 in the Orange Book, they wouldn't have been  3 eligible for inclusion on the formulary.  4 That's what you're referring to  5 there?  6 MR. HANSEL: Object to the form.  7 A. If they were not listed -- if  8 they did not meet the criteria for approval  9 and were not listed in the Orange Book as  10 therapeutically equivalent, they -- they  11 may not have been included -- well, they  12 would not have been included in the  13 formularies if they're not in the Orange  14 Book as equivalent to the Reference Listed  15 Drug.  16 Q. And then looking at paragraph  17 Roman Numeral XII, still on page 23, you  18 state that: "An ANDA would not have been  19 issued if the presence of the contaminant  20 was known because the presence of the  21 contaminant would have been inconsistent in  22 ingredients to the RLD, and thus would not  23 receive approval by the FDA"; correct?  24 A. That's what -- yes, that's what  25 it says.</p>
<p style="text-align: right;">Page 183</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 medications if they were aware of the  3 potential presence of NDMA or NDEA within  4 these products?  5 A. They wouldn't have paid for the  6 medications because the medication would  7 not have been considered for inclusion on  8 their formulary or any formulary if they  9 did not -- if the drug did not meet the  10 sameness, the safety, the effectiveness to  11 the original drug product or the Reference  12 Listed Drug, would not have met the  13 criteria for approval or the ongoing  14 obligation.  15 Certainly would not have been in  16 the Orange Book, and so it would not have  17 been considered for inclusion to the  18 formularies and the TPPs would not have  19 paid for the contaminated medications.  20 It wouldn't be on the formulary,  21 wouldn't pay for them.  22 Q. Okay. So essentially what this  23 paragraph 10 refers to is that if the VCDs  24 had never been approved or if they had not  25 been listed as therapeutically equivalent</p>	<p style="text-align: right;">Page 185</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 Q. And is the contaminant that is  3 referenced in this paragraph 12, is that,  4 again, NDMA and/or NDEA?  5 A. Yes.  6 Q. What is your basis for stating  7 in this paragraph that "presence of NDMA  8 and/or NDEA would have been inconsistent in  9 ingredients to the RLD"?  10 A. The FDA issued a recall on these  11 drugs because there were contaminants,  12 human carcinogens found.  13 That deviation, that component  14 was inconsistent with the Reference Listed  15 Drug product. Not the same, not safe,  16 certainly not safe or effective.  17 Q. Do you know whether the recall  18 or recalls were issued by the FDA or by the  19 individual drug companies?  20 A. The recalls were issued by the  21 FDA.  22 Q. What's your basis for that?  23 A. The FDA website. Information on  24 the FDA website regarding the recalls.  25 Q. Is that information that you're</p>


<p style="text-align: right;">Page 186</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph. 2 referencing, is that included among your 3 Appendix A references? 4 A. Yes. 5 Q. Which one is it? 6 A. Page 4, fifth down, fifth and 7 sixth refer to drug recall, and the fifth 8 one down, and then the sixth one is a 9 reference to the USFDA site regarding the 10 Agency's statement on the medications and 11 their safety issues. 12 Q. And it's your testimony that 13 these references indicate that the FDA 14 initiated these recalls? 15 A. The FDA issued the recalls. 16 Q. Let me ask this: 17 What do you mean by "the FDA 18 issued the recalls"? 19 A. They made known that there was a 20 carcinogen, that the medications were 21 contaminated. They put out a notice as 22 such, informing the public, essentially, 23 that the products are contaminated with a 24 human carcinogen. 25 Q. Would you take issue with the</p>	<p style="text-align: right;">Page 188</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph. 2 A. No. 3 Q. Do you know whether there were 4 certain lots of VCDs that did not contain 5 any detectible NDMA and/or NDEA but were 6 recalled nevertheless? 7 A. I'm not sure. They could have 8 been. When you say "lots" -- repeat the 9 question, please. 10 (Requested portion of record 11 read.) 12 A. The FDA issued the lots and NDCs 13 and effective manufacturers for the recall 14 as part of the recall, the ones that they 15 identified as part of their recall, and 16 those are the ones I would refer to. 17 Q. Do you know one way or the other 18 whether there were any lots of any VCD that 19 were subject to recall but that did not 20 contain any detectible NDMA and/or NDEA? 21 A. That's not within my scope. 22 The affected lots, manufacturers 23 and VCDs that the FDA recalled were part of 24 the notice, and those are the ones I'm 25 referring to.</p>
<p style="text-align: right;">Page 187</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph. 2 representation that the individual drug 3 companies initiated the recalls of their 4 respective products? 5 A. They -- if you're saying that 6 the drug companies initiated the recalls -- 7 I'm not clear who you're saying they 8 initiated those to, if they did. 9 Q. Have you reviewed the recall 10 notices for any of the VCDs at issue in 11 this litigation? 12 A. I have seen the notices. 13 Q. Are you aware that they were 14 voluntary recalls by the drug companies? 15 A. I am aware. 16 Q. Are you aware of whether there 17 was -- are you aware one way or the other 18 of whether there was ever any recall of the 19 RLD product? 20 A. That was outside the scope of my 21 report, no. 22 Q. Do you have any knowledge as to 23 the levels of NDMA and/or NDEA that were 24 found in any particular lot of any 25 particular VCD?</p>	<p style="text-align: right;">Page 189</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph. 2 Q. Okay. So when you say that's 3 not within your scope, does that mean you 4 do not know one way or the other whether 5 there were any lots of any VCD that were 6 subject to recall, but did not contain any 7 detectible NDMA and/or NDEA? 8 MR. MESTRE: Object to the form. 9 A. If they were subject to recall 10 by the FDA, the assumption is that they had 11 contaminants in their product. 12 Q. Do you know one way or the other 13 the results of the testing for NDMA and/or 14 NDEA of each lot of each VCD that was 15 subject to recall? 16 MR. MESTRE: Object to the form. 17 A. No, I'm not a toxicologist. 18 Q. So you don't know one way or the 19 other whether any of those lots might have 20 had a level that was not detectible? 21 MR. HANSEL: Object to the form. 22 A. The products that were 23 recalled -- the lots, the NDCs, the 24 manufacturers -- the FDA deemed not safe 25 and with a human carcinogen, not</p>

<p style="text-align: right;">Page 190</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 inconsistent -- not being the same as the  3 drug, original drug product, brand,  4 Reference Listed Drug.  5 This is the main point.  6 Q. Doctor, again, you didn't review  7 the individual recall notices?  8 MR. HANSEL: Object to the form.  9 A. No, I believe I answered that I  10 have seen the recall notices.  11 Q. You have not reviewed any test  12 results for any of the lots of VCDs that  13 were subject to recall; correct?  14 A. I responded no, I'm not a  15 toxicologist. That's not within the scope  16 of this report.  17 Q. And so therefore you don't know  18 one way or the other whether those results  19 were undetectable or something else?  20 MR. HANSEL: Object to the form.  21 A. Any contaminant is still a  22 contaminant, is still a carcinogen and is  23 still an adulterated product.  24 It's still a deviation from the  25 original, not the same and not safe in any</p>	<p style="text-align: right;">Page 192</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 Q. So, no, you're not aware one way  3 or the other?  4 MR. HANSEL: Same objection.  5 You could answer.  6 A. No.  7 MS. ISIDRO: Doctor, I don't  8 have any further questions for you at  9 this time. There may be other  10 attorneys and plaintiffs' counsel may  11 have questions for you.  12 THE WITNESS: Thank you.  13 MR. HANSEL: Why don't we take a  14 short break.  15 THE VIDEOGRAPHER: This will end  16 Media Unit 5.  17 Going off the record at 5:19.  18 (A recess was taken.)  19 THE VIDEOGRAPHER: We are back  20 on the record.  21 The time is 5:26.  22 This will begin Media Unit 6.  23 EXAMINATION BY  24 MR. KASPARIE:  25 A. Hi.</p>
<p style="text-align: right;">Page 191</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 amount that the FDA issued a recall for.  3 Q. But, again, you don't know what  4 amount, if any, was found in any particular  5 lot of any VCD; correct?  6 MR. HANSEL: Objection.  7 Asked and answered repeatedly.  8 MR. MESTRE: Beyond the scope.  9 A. It is beyond the scope and I --  10 any amount of a carcinogenic toxin,  11 contaminant is -- that rendered the drug  12 not the same as its original product, that  13 drug is therefore not safe for use.  14 Q. Do you have personal knowledge  15 of each and every lot, each and every VCD  16 that was subject to recall, having a  17 detectable level of NDMA and/or NDEA?  18 MR. HANSEL: Object to the form.  19 A. No, that is outside my scope.  20 Q. Are you aware whether any  21 manufacturer of any VCD tested its VCDs for  22 its finished product VCDs for nitrosamines?  23 A. No.  24 MR. HANSEL: Object to the form.  25 Foundation.</p>	<p style="text-align: right;">Page 193</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 Q. Hi, Dr. Panagos.  3 As I think was just briefly  4 mentioned, my name is Alex Kasparie. I  5 represent the ZHP defendants in this case  6 and I just have a couple of questions  7 following up on other defense counsel's  8 questions.  9 My first question is, and to  10 confirm, are you offering -- rather, to  11 confirm, you are not offering any opinions  12 about ZHP specifically; correct?  13 MR. HANSEL: Object to the form.  14 I'll just advise Dr. Panagos to  15 take your time, look through your  16 report as much as you may need to do.  17 That's a very broad question.  18 THE WITNESS: It is, it is a  19 broad question.  20 BY MR. KASPARIE:  21 Q. So let me ask this follow-up  22 question.  23 Are you offering any opinions  24 specifically regarding ZHP's compliance  25 with CGMP as an API manufacturer?</p>



<p style="text-align: right;">Page 194</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 MR. HANSEL: Object to the form.</p> <p>3 MR. MESTRE: Object to the form.</p> <p>4 A. Among the defendants here is</p> <p>5 ZHP.</p> <p>6 Q. Okay. And so what opinions</p> <p>7 specifically are you offering regarding</p> <p>8 ZHP?</p> <p>9 MR. HANSEL: Object to the form.</p> <p>10 I'm sorry, Attorney Kasparie,</p> <p>11 but the report --</p> <p>12 MR. KASPARIE: Listen, I'm not</p> <p>13 trying to make this difficult. I just</p> <p>14 want to make --</p> <p>15 MR. HANSEL: The report talks</p> <p>16 about defendants.</p> <p>17 Are you asking whether ZHP is</p> <p>18 stated by name or are you asking for</p> <p>19 every opinion the witness has offered</p> <p>20 about all defendants including ZHP?</p> <p>21 MR. KASPARIE: I'm asking --</p> <p>22 BY MR. KASPARIE:</p> <p>23 Q. All right. Let me put it this</p> <p>24 way: Dr. Panagos, are you offering</p> <p>25 testimony regarding drug product</p>	<p style="text-align: right;">Page 196</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 not the -- can I just ask my -- she</p> <p>3 can respond to my question.</p> <p>4 If you want to object to it,</p> <p>5 that's fine, but I'd like an answer to</p> <p>6 it. So my question is, she just said</p> <p>7 that API manufacturers were not within</p> <p>8 the scope of her -- well, let me ask</p> <p>9 this.</p> <p>10 BY MR. KASPARIE:</p> <p>11 Q. Are API manufacturers, Dr.</p> <p>12 Panagos, within the scope of your report?</p> <p>13 MR. HANSEL: Object to the form.</p> <p>14 A. Yes, they're part -- they're</p> <p>15 part of the report and they're part of the</p> <p>16 manufacturer and they're part of the ANDA</p> <p>17 process, so they're part of the report.</p> <p>18 The responsibility is still --</p> <p>19 and accountability still lies with the</p> <p>20 manufacturer.</p> <p>21 Q. You just testified, though, that</p> <p>22 API manufacturers, or that your report</p> <p>23 concerns ANDA -- manufacturers that</p> <p>24 submitted ANDAs; correct?</p> <p>25 MR. HANSEL: Object to the form.</p>
<p style="text-align: right;">Page 195</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 manufacturers or drug substance</p> <p>3 manufacturers?</p> <p>4 MR. MESTRE: Object to the form.</p> <p>5 MR. HANSEL: Object to the form.</p> <p>6 A. My opinions are referring to the</p> <p>7 manufacturers who submitted the ANDA.</p> <p>8 Q. Okay. And are you aware -- and</p> <p>9 are you aware if API manufacturers submit</p> <p>10 ANDAs?</p> <p>11 A. API manufacturers were not</p> <p>12 within the scope of my report here.</p> <p>13 Q. So then to confirm, you are not</p> <p>14 offering any opinions regarding ZHP's</p> <p>15 actions as an API manufacturer?</p> <p>16 MR. HANSEL: Object to the form.</p> <p>17 BY MR. KASPARIE:</p> <p>18 Q. Did you just say "correct," Dr.</p> <p>19 Panagos?</p> <p>20 A. No, I did not.</p> <p>21 MR. HANSEL: Attorney Kasparie,</p> <p>22 with a broad brush question you're not</p> <p>23 going to erase her expert report and</p> <p>24 everything it says.</p> <p>25 MR. KASPARIE: Counsel, that's</p>	<p style="text-align: right;">Page 197</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 A. Please take my last response as</p> <p>3 clarification to what you just stated.</p> <p>4 Q. All right.</p> <p>5 MR. KASPARIE: Can we read back</p> <p>6 Dr. Panagos's response to my question</p> <p>7 -- her response regarding the ANDA</p> <p>8 manufacturers.</p> <p>9 MR. HANSEL: Object to the form.</p> <p>10 MR. KASPARIE: The question and</p> <p>11 the response, please.</p> <p>12 (The following question and</p> <p>13 answer was read back:</p> <p>14 "Question: Dr. Panagos, are you</p> <p>15 offering testimony regarding drug</p> <p>16 product manufacturers or drug</p> <p>17 substance manufacturers?</p> <p>18 "Answer: My opinions are</p> <p>19 referring to the manufacturers who</p> <p>20 submitted the ANDA.")</p> <p>21 BY MR. KASPARIE:</p> <p>22 Q. And so, Dr. Panagos, are you</p> <p>23 recanting that testimony?</p> <p>24 MR. HANSEL: Object to the form.</p> <p>25 THE WITNESS: I'm sorry, could</p>

<p style="text-align: right;">Page 198</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 you read that question again.  3 Thank you.  4 (The following question was read  5 back: "Question: Dr. Panagos, are  6 you offering testimony regarding drug  7 product manufacturers or drug  8 substance manufacturers?")  9 A. My report and the opinions in my  10 report are for the manufacturers that had  11 contaminants in their drug product, and  12 therefore their product was not equal, same  13 or safe to the Reference Listed Drug  14 product.  15 MR. KASPARIE: Can we take  16 literally a two-minute break?  17 MR. HANSEL: Sure.  18 THE VIDEOGRAPHER: Going off the  19 record. The time is 5:34.  20 (A recess was taken.)  21 THE VIDEOGRAPHER: We are back  22 on the record at 5:40.  23 MR. KASPARIE: Could I ask the  24 court reporter just to read the last  25 question and answer from just before</p>	<p style="text-align: right;">Page 200</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 involved in the manufacture of  3 valsartan-containing drugs?  4 MR. MESTRE: Object to the form.  5 MR. HANSEL: Take your time.  6 Object to the form. Take your time to  7 review your report.  8 A. In my report and in the Orange  9 Book, 1.2 subset 5, I refer to Good  10 Manufacturing Practices.  11 Anyone involved with the  12 deviation of a Good Manufacturing Practice  13 would fall -- with regards to these drugs,  14 any manufacturer would be part.  15 Q. So but you can't point me to a  16 specific paragraph number in your report  17 where you make the representation that any  18 person who is involved in the manufacturing  19 of valsartan-containing drugs is the  20 subject of your report?  21 MR. HANSEL: Excuse me, object  22 to the form. You know, this is a  23 lengthy report. It's 23 pages long,  24 double-spaced.  25 Attorney Kasparie, you know what</p>
<p style="text-align: right;">Page 199</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 we took the break.  3 (The following question and  4 answer was read back:  5 "Question: And so, Dr. Panagos,  6 are you recanting that testimony?  7 "Answer: My report and the  8 opinions in my report are for the  9 manufacturers that had contaminants in  10 their drug product, and therefore  11 their product was not equal, same or  12 safe to the Reference Listed Drug  13 product.")  14 BY MR. KASPARIE:  15 Q. Just one final question, Dr.  16 Panagos, I hope.  17 By "drug product," you're  18 referring to finished dose  19 valsartan-containing drugs; right?  20 MR. HANSEL: Object to the form.  21 A. I'm referring to anyone involved  22 in the process with regard to that drug  23 product and the manufacturers.  24 Q. Where in your report do you  25 state that you're referring to everyone</p>	<p style="text-align: right;">Page 201</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.  2 the report says. You've studied it  3 thoroughly. If you would like the  4 witness to read every line of the  5 report right now and tell you where it  6 refers to what you're asking about,  7 then we can go off the record and come  8 back in 45 minutes and she will tell  9 you where she found the references  10 that you are familiar with.  11 MR. KASPARIE: Let me put it  12 this way. Listen, I am not interested  13 in wasting anyone's time here. I just  14 need an answer whether or not Dr.  15 Panagos -- let me back up.  16 BY MR. KASPARIE:  17 Q. Your report discusses  18 valsartan-containing drug manufacturers;  19 correct?  20 A. Correct.  21 Q. Does the term "API manufacturer"  22 appear in your report?  23 MR. HANSEL: Object to the form.  24 Take your time.  25 MR. MESTRE: Object to the form.</p>

<p style="text-align: right;">Page 202</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 Asked and answered and</p> <p>3 misleading.</p> <p>4 A. Page 3, number 20.</p> <p>5 Q. Where in that line is the term</p> <p>6 "API"?</p> <p>7 A. Number 20.</p> <p>8 Q. And just to go back, just to</p> <p>9 clarify the record, you talk about "many of</p> <p>10 these VCDs were manufactured, distributed</p> <p>11 or sold by active pharmaceutical ingredient</p> <p>12 and finished dose manufacturers"; correct?</p> <p>13 MR. HANSEL: You want to read</p> <p>14 the rest of the sentence?</p> <p>15 MR. KASPARIE: Sorry, could</p> <p>16 you --</p> <p>17 BY MR. KASPARIE:</p> <p>18 Q. Do you agree that there's a</p> <p>19 difference between a valsartan-containing</p> <p>20 drug and the API which that drug contains?</p> <p>21 MR. HANSEL: Object to the form.</p> <p>22 A. Again, my report is referring to</p> <p>23 the manufacturers, including anyone</p> <p>24 involved whereby there were contaminants in</p> <p>25 the drug that rendered the drug not the</p>	<p style="text-align: right;">Page 204</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 move on to any additional questioners.</p> <p>3 Any other defendants' questions?</p> <p>4 MS. ISIDRO: Anyone else on</p> <p>5 Zoom?</p> <p>6 MR. HANSEL: Plaintiffs have no</p> <p>7 questions. Thank you.</p> <p>8 MS. ISIDRO: Thank you.</p> <p>9 THE WITNESS: Thank you.</p> <p>10 MR. HANSEL: Thank you, Dr.</p> <p>11 Panagos, for your time.</p> <p>12 THE VIDEOGRAPHER: This will end</p> <p>13 Media Unit 6 and conclude the</p> <p>14 deposition of Dr. Kali Panagos.</p> <p>15 We are going off the record at</p> <p>16 5:51, 1/11/23.</p> <p>17 (Time Noted: 5:51 p.m.)</p> <p>18</p> <p>19 KALIOPI PANAGOS, PharmD, R.Ph.</p> <p>20 Subscribed and sworn to on the ____ day of</p> <p>21 _____, 20 ____ before me.</p> <p>22</p> <p>Notary Public,</p> <p>23 in and for the State of</p> <p>24 _____.</p> <p>25</p>
<p style="text-align: right;">Page 203</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 same, safe or effective.</p> <p>3 MR. KASPARIE: I think that's</p> <p>4 all the questions I have, but I'm</p> <p>5 going to make a note that we may move</p> <p>6 to reopen this deposition if</p> <p>7 plaintiffs interpret what Dr. Panagos</p> <p>8 just testified to is that her report</p> <p>9 is regarding the CGMP of the API</p> <p>10 manufacturers, as well as the drug</p> <p>11 substance manufacturers, and we also</p> <p>12 move to strike any of the opinions</p> <p>13 that she just offered that are not</p> <p>14 disclosed in the report.</p> <p>15 MR. HANSEL: I object to your</p> <p>16 statement.</p> <p>17 This is your day with Dr.</p> <p>18 Panagos. There's time today. We're</p> <p>19 not going to hold this deposition</p> <p>20 open.</p> <p>21 The report says what it says.</p> <p>22 If you want to ask her about it,</p> <p>23 today's your day. And we object to,</p> <p>24 you know, trying to hold that over her</p> <p>25 head. But if you're finished, we'll</p>	<p style="text-align: right;">Page 205</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 C E R T I F I C A T E</p> <p>3</p> <p>4 I, Linda J. Greenstein, Professional</p> <p>5 Shorthand Reporter and Notary Public in and</p> <p>6 for the State of New York, do hereby</p> <p>7 certify that, KALIOPI PANAGOS, PharmD,</p> <p>8 R.Ph., the witness whose deposition is</p> <p>9 hereinbefore set forth, was duly sworn and</p> <p>10 that such deposition is a true record of</p> <p>11 the testimony given by the witness to the</p> <p>12 best of my skill and ability.</p> <p>13 I further certify that I am neither</p> <p>14 related to or employed by any of the</p> <p>15 parties in or counsel to this action, nor</p> <p>16 am I financially interested in the outcome</p> <p>17 of this action.</p> <p>18 IN WITNESS WHEREOF, I have hereunto set</p> <p>19 my hand this 22nd day of January 2023.</p> <p>20</p> <p>21 </p> <p>22 Linda J. Greenstein</p> <p>23</p> <p>24 My commission expires: January 30, 2025</p> <p>25</p>

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<p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph. 2 I N D E X 3 4 WITNESS EXAMINED BY PAGE 5 KALIOPI PANAGOS, Ms. Isidro 10 PharmD, R.Ph. 6 Mr. Kasparie 192 7 8 ----- INFORMATION REQUESTS ----- 9 10 DIRECTIONS NOT TO ANSWER: 11 Page Line 12 (NONE) 13 REQUESTS: 14 Page Line 15 (NONE) 16 17 ----- E X H I B I T S ----- 18 NO. PAGE 19 (Exhibit 1 marked for 13 20 identification, multi-page 21 document, deposition notice for 22 Kaliopi Panagos.) 23 (Exhibit 2 marked for 15 24 identification, multi-page 25 document, plaintiffs' objections/responses to deposition of Kaliopi Panagos.) (Exhibit 3 marked for 16 identification, four-page document, CV of Kaliopi Panagos.) (Exhibit 4 marked for 17 identification, four-page document, Appendix B to CV of Kaliopi Panagos.) 24 25</p>	<p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph. 2 DEPOSITION ERRATA SHEET 3 4 Our Assignment No.: 5625215 5 Case Caption: In Re Valsartan 6 7 DECLARATION UNDER PENALTY OF PERJURY 8 9 I declare under penalty of 10 perjury that I have read the entire 11 transcript of my Deposition taken in the 12 captioned matter or the same has been read 13 to me, and the same is true and accurate, 14 save and except for changes and/or 15 corrections, if any, as indicated by me on 16 the DEPOSITION ERRATA SHEET hereof, with 17 the understanding that I offer these 18 changes as if still under oath. 19 20 KALIOPI PANAGOS, PharmD, R.Ph. 21 Subscribed and sworn to on the ____ day of 22 _____, 20 ____ before me. 23 24 Notary Public, 25 in and for the State of _____.</p>
<p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph. 2 C O N T I N U E D 3 I N D E X: 4 ----- E X H I B I T S ----- 5 NO. PAGE 6 (Exhibit 5 marked for 30 7 identification, multi-page 8 document, Appendix A to CV of 9 Kaliopi Panagos.) 10 (Exhibit 6 marked for 49 11 identification, multi-page 12 document, Expert Report of 13 Kaliopi Panagos.) 14 (Exhibit 7 marked for 52 15 identification, four-page 16 document, Kaliopi Panagos 17 invoices.) 18 (Exhibit 8 marked for 95 19 identification, five-page 20 document titled "Abbreviated New 21 Drug Application (ANDA) Forms and 22 Submission Requirements.") 23 (Exhibit 9 marked for 113 24 identification, multi-page 25 document titled "Orange Book Preface.") (Exhibit 10 marked for 124 identification, multi-page document titled "AMCP Formulary Management.") (Exhibit 11 marked for 142 identification, multi-page document titled "ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System.") (Exhibit 12 marked for 171 identification, two-page document titled "Medication Guides.") (Exhibit 13 marked for 176 identification, multi-page document titled "Medication Guides.") 24 25</p>	<p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph. 2 DEPOSITION ERRATA SHEET 3 Page No. ____ Line No. ____ Change to: ____ 4 5 Reason for change: ____ 6 Page No. ____ Line No. ____ Change to: ____ 7 8 Reason for change: ____ 9 Page No. ____ Line No. ____ Change to: ____ 10 11 Reason for change: ____ 12 Page No. ____ Line No. ____ Change to: ____ 13 14 Reason for change: ____ 15 Page No. ____ Line No. ____ Change to: ____ 16 17 Reason for change: ____ 18 Page No. ____ Line No. ____ Change to: ____ 19 20 Reason for change: ____ 21 Page No. ____ Line No. ____ Change to: ____ 22 23 Reason for change: ____ 24 25</p>

<p style="text-align: right;">Page 210</p> <p>1 CONFIDENTIAL - K. PANAGOS, PharmD, R.Ph.</p> <p>2 DEPOSITION ERRATA SHEET</p> <p>3 Page No.____Line No.____Change to:_____</p> <p>4 _____</p> <p>5 Reason for change:_____</p> <p>6 Page No.____Line No.____Change to:_____</p> <p>7 _____</p> <p>8 Reason for change:_____</p> <p>9 Page No.____Line No.____Change to:_____</p> <p>10 _____</p> <p>11 Reason for change:_____</p> <p>12 Page No.____Line No.____Change to:_____</p> <p>13 _____</p> <p>14 Reason for change:_____</p> <p>15 Page No.____Line No.____Change to:_____</p> <p>16 _____</p> <p>17 Reason for change:_____</p> <p>18 Page No.____Line No.____Change to:_____</p> <p>19 _____</p> <p>20 Reason for change:_____</p> <p>21 Page No.____Line No.____Change to:_____</p> <p>22 _____</p> <p>23 Reason for change:_____</p> <p>24 _____</p> <p>25 _____</p>	

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## Federal Rules of Civil Procedure

## Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

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COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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